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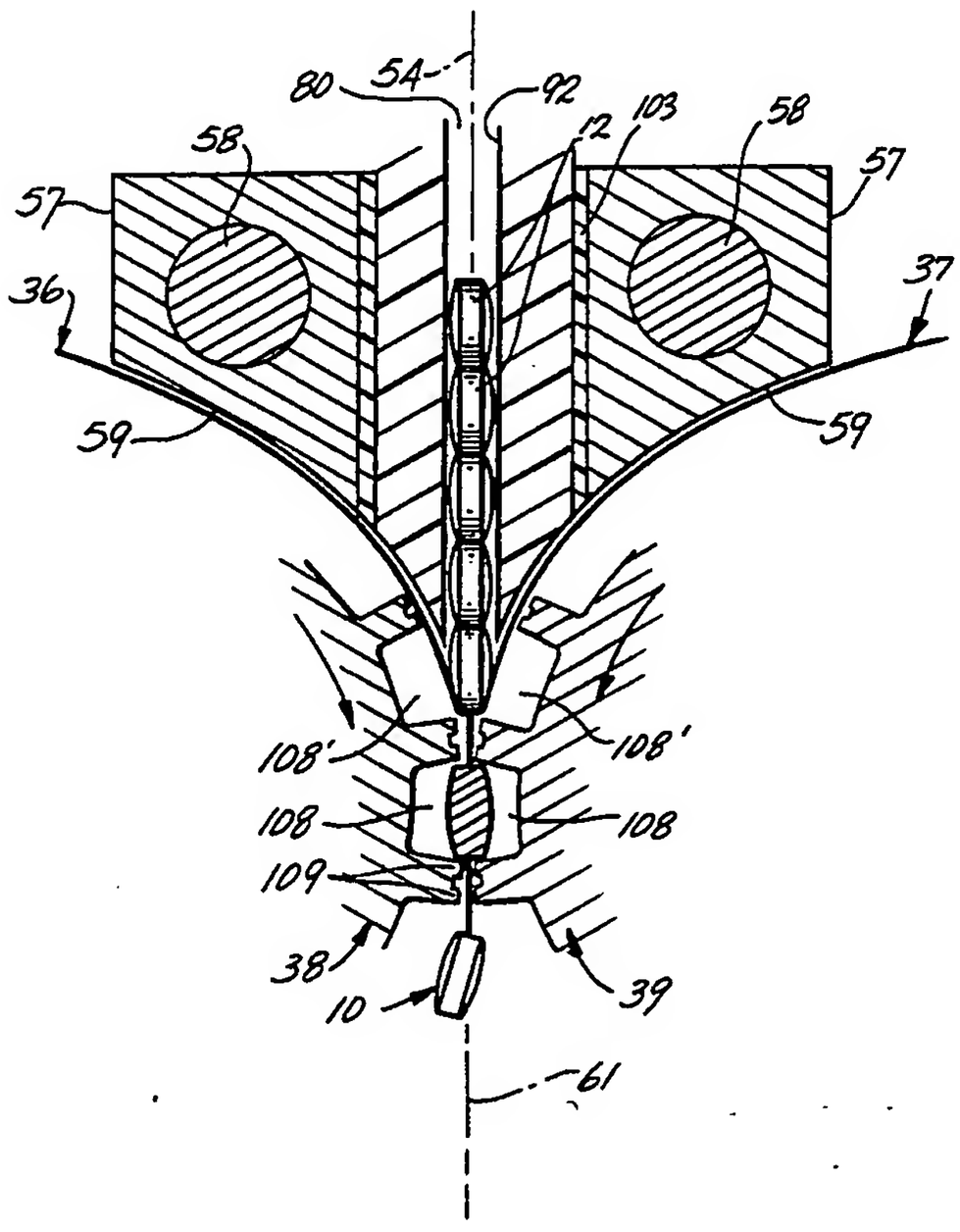
(57) Abstract

A medicine tablet (10) has a preformed unitary core (13) enrobed by a hard gelatin coating (12) which is stretched around the core and is sealed in edge-to-edge manner at all locations along a seam (15) which encircles the core. The enrobed tablet is made by introducing a core into contact with two plastic and elastic gelatin films (36, 37) at a nip between two rotary discs (38, 39) across the recessed (108) surfaces of which the films are tensioned. The core is contacted with the films at locations over the recesses so that die rotation causes the films to stretch in the recesses around the core into conformance with the contours and to seal to each other along the seal line. The films are then severed along that line. The films, as applied to the core, adhere tightly to the core and dry to a hard state.



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FILM-ENROBED UNITARY-CORE MEDICAMENT AND THE LIKE

Field of the Invention

This invention pertains to film-enrobed unitary-core products such as medicine tablets, to films and film compositions for making such products, and to methods and equipment for manufacturing such products. More specifically, it pertains to medicines and the like comprising cores of one-piece tablet nature in various shapes which are enrobed in digestible or erodable films applied after formation of the cores. It also pertains to gelatin-based and other films for enrobing such cores, to methods for enrobing such cores with such films, and to equipment for performing such methods to produce such products.

Background of the Invention

It is known to dip or spray tablet-type medicine dosage units with gelatin or other materials to make them more palatable, easier to swallow, less prone to powder or to flake when handled in bottles, colored for eye appeal or identifiability, and longer lasting before active ingredients degrade, among other reasons. Capsule forms of such products occur as soft gelatin capsules, which commonly are of spherical or oblate spherical shape, and as hard gelatin capsules which commonly are of elongated round-ended cylindrical form and which are made in two pieces for assembly, with or without sealing, around the flowable fill material containing the desired active ingredients.

The portion of U.S. Patent 4,820,524 entitled "Background of the Invention" (which portion is incorporated herein by reference) presents a comprehensive review of hard gelatin encapsulated medicines and the like, and of certain forms of solid medicaments having spray-applied or dip-applied gelatin coatings. Because of the problem of tampering which had been experienced with hard gelatin capsule products, many manufacturers of such products withdrew them from the market in favor of other forms of active-ingredient presentment, notably caplets. The withdrawal of hard gelatin encapsulated products from the market left those manufacturers with idle machines for making hard gelatin capsules, a situation which Patent 4,820,524 addressed by its descriptions of how such machinery could be modified to produce an at least twice-dipped, gelatin-coated caplet form of medicine. The resulting final product can be colored uniformly, or it can be colored differently at its opposite ends by differently tinting the gelatin baths into which each of the opposite ends of the caplet preform is dipped at least once. A number of advantages of such products over hollow hard gelatin capsules and over pan-coated tablets are noted in Patent 4,820,524 at column 11, lines 19 et seq.

In its detailed description, namely, at column 10, lines 47 et seq., Patent 4,820,524 notes that the dipping of preformed caplets into wet gelatin baths can have disadvantageous effects, and that precoating of the caplet with a sealant, such as a moisture barrier, can be useful.

While the procedures described in Patent 4,820,524 for producing at least twice-dipped, gelatin-coated caplets are relatively simple, the machinery required for high-volume implementation of those procedures is quite complex, extensive and expensive. Also, those procedures and that machinery are not well suited for handling solid medicament preforms in shapes other than caplet shape.

U.S. Patents 2,663,128 (1953), 2,697,317 (1954), and 2,775,080 (1956), all issued to F.E. Stirin and A.S. Taylor as assignors to American Cyanamid Company, describe complex procedures and equipment in which a suitable active ingredient powder is formed into a soft pellet. The pellet is transferred into a cup-like depression formed by vacuum in a plastic gelatin film. The cup-like depression can also contain a liquid. The film which defines the loaded depression is moved into contact with a second gelatin film which is sealed across the depression. The loaded and sealed depression is cut from the adhered pair of films, and the product then self-adjusts its shape to a desired tablet, sphere, or capsule-like shape, after which it is processed similarly to a conventional soft encapsulated gelatin capsule.

More recently (Packaging Technology, March/April 1987, Vol 17, No. 2, pp. 4, 7 and 16), equipment and methods for encasing a pair of half-dose softly-compacted tablet-like preforms between converging soft elastic gelatin films have been described. So far as is known, such equipment was not successfully built and operated.

A need exists for a way for the soft elastic gelatin capsule industry to support and service the tablet manufacturing industry in providing improved film enrobed tablets without disturbing the existing working relationships between those industries. This invention addresses those needs and, in so doing, provides an improved tablet product.

Summary of the Invention

This invention provides an improved dosage form, among other kinds of products, in which a solid tablet preform or core is fully enrobed in soft elastic film material, such as a gelatin film, in a relatively dry state and at relatively low temperature. Formation of the tablet can occur at times and at places segregated from the time and place where the tablet is film-enrobed. The substantially dry and low temperature nature of the tablet enrobing process is important to the integrity and life of the active ingredients in the tablet. The film enrobing the tablet can tightly bond to the tablet so that, especially when the film is distinctively colored, the enrobed tablet is tamper-evident. The enrobing films can be colored to produce monocolored or bicolored enrobed tablets. The enrobed tablets can be further processed to have enteric coatings so that when swallowed, the tablets pass through the stomach and dissolve in the intestines; the enrobing film can protect the tablet from undesirable reactions with constituents of the enteric or other coatings applied over the film. The enrobed tablet can have significantly more strength and resistance to breakage when handled or subsequently processed than the unenrobed tablet.

This invention also provides improved film compositions for use in enrobing tablets and other things for various purposes. The compositions include a soft elastic gelatin film

compositions which provides a securely bonded enrobement around a solid tablet, thereby providing a tablet having enhanced tamper-evident properties.

The invention also provides improved methods and equipment which are readily adaptable to and implementable with existing procedures and machinery in the soft elastic gelatin capsule manufacturing industry to produce the improved tablets described above. Implementation and practice of these aspects of the invention does not require large scale replacement, reworking or remanufacture of existing soft elastic gelatin encapsulation machinery or procedures, and can be accomplished rapidly and efficiently without disruption of established business practices and relationships.

According to a product aspect of the invention, there is provided an enrobed tablet having a core within a coating of ingestible, substantially solidified polymer. The coating is characterized by two applied layers of preformed film of the polymer which are sealed together along and terminate at a line encircling the core and which conform to and tightly adhere to the core without openings in the coating.

According to a further product aspect of the invention, there is provided a gelatin enrobed tablet having a tablet core and a gelatin-based coating enrobing the core. The coating is characterized by two layers of preformed gelatin which are sealed together and terminate at a line encircling the core. The coating is further characterized by having one or more of the following characteristics: it is comprised of gelatin and a plasticizer present in a weight ratio of from about 3:1 to about 15:1, it conforms to the core contours and has no openings in it, it tightly adheres to the core and is hard in the finished tablet, it tightly adheres to the core and has its seal line either substantially aligned with a plane of symmetry of the core or substantially disposed in a plane which includes an axis of symmetry of the core, or it adheres sufficiently tightly to the core that it cannot mechanically be removed from the core without removal of a part of the core.

Another preferred aspect of the invention provides an improved soft elastic gelatin composition useful to form the enrobing film for the presently preferred article of manufacture. The composition comprises gelatin and a plasticizer in a weight ratio of from about 3:1 to about 15:1, the balance being comprised of water and such pigments as may be desired.

According to a method aspect of the invention, there is provided a method for enrobing an article preform such as a medicine tablet with a substantially solidified polymer, in which at least two sheets of a substantially solidified polymer are drawn together to form a nip between the converging sheets, and a complete article preform is dispensed into the nip of the converging sheets. The method is characterized by the steps of sealing together the converging polymer sheets about the dispensed preform essentially along a line about and closely contiguous to the preform to enrobe the preform at least partially in the polymer, and separating the enrobed preform essentially along said line from the sheets.

According to another method aspect of the invention, there is provided a method for enrobing an article preform such as a medicine tablet with a substantially solidified polymer, in which at least two sheets of a substantially solidified polymer are drawn together to form

a nip between the converging sheets. The method is characterized by the steps of placing a stack of complete article preforms in contact at one end with at least one of the converging sheets adjacent to the nip so that the end preform of the stack in contact with a sheet is grabbed and drawn into the nip by at least one of the converging sheets, and sealing the two converging polymer sheets about the grabbed and drawn preform to enrobe the preform at least partially in the sheets.

According to a further method aspect, there is provided a method for enrobing an article preform such as a medicine tablet with a substantially solidified biocompatible polymer, the process being characterized by the steps of: drawing together at least two sheets of a substantially solidified biocompatible polymer to form a nip between the converging sheets, dispensing a complete article preform into the nip between the converging sheets, dispensing a complete article preform into the nip of the converging sheets, and sealing the sheets of converging polymer about the dispensed preform to enrobe the preform at least partially in the sheets.

Still another method aspect of this invention provides a method of film enrobing article preforms such as medicine tablets and the like as articles of manufacture, in which a pair of elastic and plastic gelatin-base films, which are self-adhering to the other film when at a predetermined temperature and which have obverse and reverse surfaces, are moved at essentially equal velocities along selected paths around and between a pair of matching coacting cylindrical rotary dies between which the film obverse surfaces are adjacent each other. The dies are essentially identical and each defines along at least one circumferential line a plurality of closely and uniformly spaced cavities in a surface thereof cooperable with the other die. The method is characterized by the steps of stretching the films over the die surfaces at and proximate a place of substantial coaction of the dies with each other; at a location along the film paths proximate the place of die coation, heating the obverse surface of the films to the predetermined temperature; individually dispensing a complete article preform essentially at the place of die coaction into contact with the obverse surfaces of the stretched films at locations on the films which overlie corresponding ones of the die cavities for deformation of the films into the cavities around the preform and for transporting engagement of the preform by the films; at the place of die coaction, forcefully contacting the films with each other peripherally around the preforms to cause each preform to be enrobed by and between the films, and sealing the films to each other peripherally around each preform; and separating the enrobed preforms from the films to provide the articles of manufacture each of which comprises a single preform sealed within a coating of substantially uniform thickness comprised of two gelatin layers sealed together in substantially edge to edge relation.

A first apparatus aspect of the invention provides apparatus for film enrobing article preforms of selected size and shape such as medicine tablets and the like, in which a pair of matching dies have coacting working surfaces configured to define between them, upon movement of the working surfaces into coacting relation at a selected place, at least one cavity of sufficient size and shape to receive loosely therein one of the article preforms.

Two films of selected thickness and cosealable composition are moved along respective paths which converge at the place of coaction between the die working surfaces with the films in overlying relation to the respective cavity defining features of the die working surfaces. The apparatus is characterized by means for creating in films moving along the paths predetermined conditions of plasticity and axial tension in the films as disposed at said place, and preform dispensing means located proximate the place of die coaction for presenting preforms individually to least one of the films in a selected orientation of the dispensed preforms relative to the dies at respective film locations which correspond to the die cavities, the presented preforms moving with the at least one film to the place of die coation for enrobing engagement there between the films within the die cavities. The apparatus is further characterized by means for moving the dies into and out of coacting relation at said place, the dies being formed to cause them, when moving into coacting relation, to apply the films to the preforms from opposite directions, and to seal the layers of film so applied to the preforms to each other in essentially edge-to-edge manner.

A further apparatus aspect of the invention provides an apparatus for enrobing a medicine tablet and the like with a layer of substantially solidified polymer, the apparatus being characterized by means for drawing together at least two sheets of a substantially solidified polymer to form a nip between the converging sheets, means for dispensing a tablet into the nip of the converging sheets, means for sealing together the converging polymer sheets about the dispensed tablet essentially along a line about and closely contiguous to the tablet to enrobe the tablet in the polymer, and means for separating the enrobed tablet essentially along said line from the sheets.

According to another apparatus aspect of the invention, there is provided apparatus for film enrobing article preforms of selected size and shape such as medicine tablets and the like, in which a pair of rotary dies have coacting cylindrical working surfaces each defining along a circumferential line a uniformly and closely spaced plurality of recesses each of which is cooperable with a similar recess in the other die to form a cavity of sufficient size and shape to receive loosely therein at least one of the article preforms. Two films of selected thickness and composition are moved along respective paths which converge at a place of coaction of the dies at which the films are disposed in tension in overlying relation to the respective die recesses. The apparatus is characterized by film conditioning means cooperating with the film paths adjacent each die proximate the place of die coaction for creating in films moving therealong predetermined conditions of electricity, deformability, adhesivity and axial tension in the films as disposed at said place in overlying relation to the die recesses. The apparatus is further characterized by unclocked preform dispensing means located centrally between the dies substantially at the place of die coaction for dispensing preforms individually to essentially simultaneous contact with the films at film locations overlying corresponding die recesses so that each dispensed preform moves with the films into enrobing engagement between the films within a corresponding cavity.

According to still another apparatus aspect of the invention, there is provided apparatus for film enrobing medicine tablets and the like which is characterized by means

for drawing together under axial tension, and into surface-to-surface contact at a nip location, a pair of preformed films which are elastic, plastic and capable of adhering to each other, and by means for engaging at least one of the films with a tablet to be enrobed at a location on the film which is closely adjacent the nip between the films and at which at least one film is free to deform laterally around the tablet in response to such engagement so that the tablet is taken up and drawn by the converging ilms to the nip. The apparatus is further characterized by means for stretching the converging films at the nip around the tablet and into contact with each other along a line around the tablet and substantially contiguous to it to enrobe the tablet between the films by means for sealing the films together along the line, and by means for separating the enrobed tablet from the films essentially along the line.

According to a still further aspect of the invention, the invention provides a die which is useful with a similar cooperating die for enrobing between a pair of films of soft elastic material of selected thickness individual ones of a plurality of essentially identical medicine tablets and the like. The die comprises a drum-like article which is rotatable in a selected direction about an axis. The die has a cylindrical outer working surface in which are formed, at regularly spaced intervals along at least one line circumferentially about the working surface, a plurality of essentially identical recesses. Each recess has an opening shaped geometrically similarly to the geometry of one of the tablets and each recess is dimensioned to be oversize relative to the tablet. Each recess is bounded by a rim which conforms to the shape of the recess opening. The rim of each recess, at least at a portion of the recess on the corresponding line of recesses towards the direction of die rotation, is relieved a selected amount away from the recess.

Brief Description of the Drawings

FIG. 1 is a top plan view of a gelatin film enrobed tablet of caplet configuration which is the presently preferred product produced by practice of this invention;

FIG.2 is an end elevation view of the gelatin film enrobed caplet shown in FIG. 1;

FIG. 3 is a cross-section view taken along line 3-3 in FIG. 2;

FIG. 4 is a cross-section view taken along line 4-4 in FIG. 3;

FIG. 5 is a side elevation view of a gelatin film enrobed caplet in which the enrobing film is uniformly colored over the entire extent of the product;

FIG. 6 is a side elevation view of a gelatin film enrobed caplet in which the enrobing film located on one side of a longitudinal plane of symmetry of the caplet is of one color, and the film lying on the other side of that plane of symmetry is of a different color;

FIG. 7 is a top plan view of a film enrobed round, but not spherical, tablet provided as another product of this invention;

FIG. 8 is a cross-section view taken along line 8-8 in FIG. 7;

FIG. 9 is a cross-section elevation view of another round tablet which is another product of this invention and which has, in top plan view, an appearance similar to that shown in FIG. 7;

FIG. 10 is a top plan view of an oval film enrobed tablet which is another product of this invention;

FIG. 11 is a cross-section view taken along line 11-11 in FIG. 10;

FIG. 12 is a cross-section elevation view of another oval tablet which, in top plan view, has a configuration like that shown in FIG. 10;

FIG. 13 is a simplified depiction of presently preferred apparatus useful to film enrobe tablets;

FIG. 14 is a simplified elevation view of tablet feeding mechanisms useful with the apparatus shown in FIG. 13;

FIG. 15 is a simplified fragmentary perspective view of a tablet feeding mechanism for a production form of the apparatus and process depicted in FIG. 13;

FIG. 16 is an enlarged perspective view of a portion of the feeding mechanism shown in FIG. 15;

FIG. 17 is a fragmentary elevation view of the presently preferred tablet guide tubes provided between the intermediate and final tablet feed mechanisms shown in simplified form in FIGS. 14 and 15;

FIG. 18 is a fragmentary, enlarged cross-sectional elevation view of the connection of the upper end of the tablet guide tube shown in FIG. 17 to the intermediate stage tablet feeder mechanism in the presently preferred production apparatus;

FIG. 19 is a fragmentary, somewhat simplified, cross-sectional elevation view of the final stage tablet feeding mechanism and die rolls in the presently preferred apparatus;

FIG. 20 is a perspective view of one of the die rolls shown in FIG. 19;

FIG. 21 is a fragmentary, enlarged plan view of a presently preferred cavity and land configuration useful in the die rolls shown in FIG. 20;

FIG. 22 is an enlarged cross-section view taken along line 22-22 in FIG. 21;

FIG. 23 is a simplified top plan view of a portion of a presently preferred mechanism for achieving proper positioning of caplet-style tablets in the final stage tablet feeding mechanism shown in FIGS. 15 and 16;

FIG. 24 is a simplified view of another tablet feeding and die arrangement;

FIG. 25 is a simplified, fragmentary, perspective view of a further tablet feeding and die arrangement which can be used in the practice of this invention; and

FIG. 26 is an enlarged, fragmentary, cross-section elevation view of another form of final stage tablet feeding mechanism.

Description of the Illustrated Embodiments

In broad terms, this invention concerns the coating of tablets, other solid dosage forms, and a variety of solids by enrobement with films of gelatin or other sealable polymers by an enrobement process which uses coacting die techniques in which the articles to be enrobed are introduced individually between two sealable films positioned between opposing matching dies configured to cause the films to stretch and deform around each introduced

article so that the films move into contact with each other, are sealed to each other and, as sealed, are severed from the film webs to provide individual film-enrobed end products.

The hermetically-sealed applied-film coating around the tablet or other solid core of the enrobed product can be treated after production for controlled release or enteric release. Due to the continuous nature of the applied-film coating, individual coated units provide an assurance of consistent product performance.

In the following description, unless the usage context indicates otherwise, the term "tablet" is used in its broad sense to mean a solid, hard, unitary pellet containing one or more active ingredients, which pellet is of such size as to be administered by an intended user and is of desired geometry; the term includes such things having caplet configuration, which things are often referred to simply as "caplets".

The product in FIGS. 1-4 has a core 11 and a hard gelatin coating 12 which fully encloses the core. The coating conforms tightly to the contours of the core and is adhered tightly to the surfaces of the core over the entire exterior surface extent of the core. Coating 12 is defined by layers 13 and 14 of soft elastic gelatin film which are applied to opposite sides of the core and which are sealed together, in an essentially edge-to-edge manner, along a seal line 15 which encircles the core. Seal line 15 preferably is substantially coincident with a longitudinal plane of symmetry 16 of the core. After being applied to and sealed together around the core, layers 13 and 14 dry to a hard glass-like state in which the coating is securely bonded to the core. The gelatin used to form layers 13 and 14 is formulated to produce such a finished coating.

Preferably, applied gelatin layers 13 and 14 are colored differently from the color of core 11 itself. If both applied coating layers are of the same color, the resulting product is a monocolored gelatin film enrobed caplet 17 shown in FIG. 5. On the other hand, if applied gelatin layers 13 and 14 have different colors, the resulting product is a bicolored gelatin film enrobed caplet 18 as shown in FIG. 6.

Gelatin layers 13 and 14 preferably are provided as portions of two soft elastic gelatin films which, as cast in the machinery described below and presented to the core for enrobement of the core, have a thickness in the range of from 0.005 inches to 0.04 inches. If equipment of different definition from that described below is used, films of substantially greater thickness can be handled. As applied to the caplet core and as dried thereon, the layers 13 and 14 are of somewhat smaller thickness.

Caplet core 11 can be manufactured to the desired size, shape, and composition at a facility segregated from the facility where gelatin film enrobement of the caplet occurs. Caplets generally are of geometrically similar configuration and are of elongate, round-ended configuration in plan view (see FIG. 1) and have a cylindrical peripheral surface 20 which has an oblong cross-sectional configuration. Surface 20 extends along the opposite sides 21 and around the opposite ends 22 and 23 of the caplet. The distance between the parallel sides 21 of the caplet is its width, and the distance between the extremities of ends 22 and 23 is the length of the caplet. The height of the caplet is the dimension of the caplet perpendicular to its width and length. As shown in FIG. 2, the caplet has curved top and

bottom surfaces 24 and 25, respectively. A caplet has three orthogonally oriented planes of symmetry. The major plane 16 of symmetry of the caplet lies parallel to the width and length of the caplet midway between the top and bottom extremities of the caplet, midway of the height of cylindrical caplet peripheral surface 20. A second caplet longitudinal plane of symmetry 16' lies parallel to the length of the caplet and perpendicular to plane 16 centrally of the width of the caplet. Plane 16 may correspond to the parting plane of the dies used to form the caplet. As shown in FIG. 2 which is an end view of caplet core 11 turned on its side, a caplet has a diagonal dimension D.

While gelatin enrobed medicinal caplets constitute the presently preferred product, the utility and operability of the invention has been demonstrated with tablet cores of other configurations. Other exemplary products include a round planform film coated tablet 27 shown in FIG. 10 which can have either an oval or elliptical cross-section as shown in FIG. 8 or the cross-sectional configuration shown in FIG. 9 in which the round core 28 has a circularly cylindrical peripheral surface 29 and substantially identical curved top and bottom surfaces 30. As shown in FIGS. 8 and 9, products 27 or 31 (FIG. 9) have an applied film coating completely around their exterior surfaces, which coatings are defined by cooperating top and bottom layers 13 and 14 of applied film which are connected together at a seam line 15 which extends circumferentially of the product at a plane of symmetry 16, which encompasses the greatest cross-sectional area of the product core. The seam line can be located at other places on the product core.

Similarly, as shown in FIGS. 10 through 12, a film enrobed product 33 or 34 can have an oval configuration when viewed from the top (see FIG. 10) and either a lengthwise cross-sectional configuration (product 33) which is the same as that shown in FIG. 8 for product 27 (see FIG. 11) or a lengthwise cross-sectional configuration (product 34) which is the same as that shown in FIG. 9 for product 31.

FIGS. 8, 9, and 10 show that the enrobed tablets there illustrated have other planes of symmetry 16' which are perpendicular to the major planes of symmetry 16 and are either disposed diametrically (FIGS. 7-9) or longitudinally (FIGS. 10-12) of the tablets. Film enrobed tablets can be produced with seam lines disposed in symmetry planes 16' of the caplet (FIGS. 1-6), round (FIGS. 7-9) and oblong or oval (FIGS. 10-12) tablets if such seam placement is desired.

An applied-film enrobed product produced by the registering, preferably rotary, die process described in greater detail below has a characteristic signature. That signature is a very slight thickening of coating 12 along seam line 15; see FIGS. 3, 4, 8, 9, 11 and 12. Principally for aesthetic reasons, it is preferred that seam line 15 lie in the major 16 or secondary 16' plane of symmetry of the core of a medicinal or similar product. Coincidence of the seam line with a plane of symmetry is particularly preferred where the applied-film enrobed product is bicolored (see product 18 in FIG. 6) for any one of various reasons including product identifiability.

FIGS. 13 through 23 illustrate the preferred process for making applied-film enrobed articles according to this invention, including the various kinds of medicine tablet products

shown in FIGS. 1 through 12. FIGS. 13 through 23 also show preferred equipment useful to practice the preferred manufacturing method. Except for the nature of the core feeding mechanism, the basic aspects of the preferred process and manufacturing equipment are shown in FIG. 13. The manufacturing process and equipment create and use first and second films 36 and 37 of soft elastic gelatin of selected thickness and composition, and a pair of matching dies 38 and 39 (which preferably are rotary dies) and between which films 36 and 37 pass adjacent the location where a core feed device 40 cooperates with at least one and preferably both of the films and dies. That is, as shown in FIGS. 24 and 25, products according to this invention can be made by use of appropriately arranged apparatus pursuant to processes in which the product cores are initially engaged with only one of the two films before the films come together between matching dies. However, in the preferred manufacturing process and manufacturing apparatus, the core feeding mechanism is arranged to introduce the cores to the films in the working area between the dies so that each core contacts both films essentially simultaneously. Except for the specifics of the dies and the core feeding mechanisms used in the practice of this invention, the machinery and processes depicted in FIG. 13 will be familiar to workers skilled in the manufacture of soft elastic gelatin capsules and in the design and operation of machinery for making such capsules.

As shown in FIG. 13, films 36 and 37 are individually cast on separate rotating casting drums 42 and 43 in a continuous manner by introduction of liquid gelatin to the outer casting surface of each drum from a liquid gelatin dispensing device 44 of known nature. Liquid gelatin is supplied to each dispensing device from a respective container 45 in which the gelatin is kept liquid at an elevated temperature by a heater 46, such as an electrical heater. Each container 45 is airtight so that liquid gelatin can be moved from the interior of the container to the adjacent gelatin dispensing device 44 through a transfer tube 47 under the effect of compressed air introduced to the container through an inlet tube 48. Gravity feed of liquid gelatin to the dispensing devices can be used, if desired.

Each casting drum 42, 43 is cooled by circulation of an appropriate coolant. Hence, the liquid gelatin introduced to the moving casting drum surface solidifies on the drum casting surface sufficiently to form film 36 or 37 adequately that the film can be led continuously from the respective casting drum to dies 38 and 39 along a desired path. The path of movement of the cast gelatin film is through a lubricant bath 50 via a roller 51 and thence to a driven tractor roll 52. The lubricant in bath 50 is applied principally to the reverse surface of the film, which will not be contacted with the other film between die rolls 38 and 39. The outer surface of tractor roll 52 preferably has a traction layer 53 which enables the traction layer to co-act without slippage with the reverse surface of the gelatin film. As the gelatin film passes from each tractor roll to the adjacent die 38 or 39, a thin layer of lubricant remains on the film reverse surface to prevent the die and the film from sticking to each other.

As shown in FIG. 13, dies 38 and 39, together with the cooperating portion of the core feed mechanism 40, are symmetrically disposed relative to each other about a functional center plane 54 of the apparatus. The portion of the core feed mechanism immediately

adjacent to the cooperating dies is a core feed horn 56 disposed upon functional center plane 54 in association with a pair of shaped metal heater blocks 57 which extend across the width of the adjacent gelatin film. Each heater block preferably includes an electrical resistance heater element 58 (see FIG. 19). The heater blocks are in close proximity to the core feed horn 56 and to the die rolls for contacting the obverse surface of the adjacent gelatin film in that portion of the film path where the film preferably then is wrapped around the adjacent die roll. The heater blocks heat the gelatin films to a desired temperature which is important to the topics of self-timing operation of the dies and feed mechanism and of the character of the enrobement of each product core by the gelatin films, both topics being discussed in greater detail below. Each heater block 57 has a curved film-contacting surface 59 for contact with the obverse surface of the moving gelatin film as closely as possible to the point at which individual product cores emerge from the lower end of the wedge-shaped lower portion of core feed horn 56 substantially at the nip of dies 38 and 39. The die nip is the place where films 36 and 37 are brought into contact with each other by the dies.

At the location where die rolls 38 and 39 and core feed horn 56 cooperate closely with each other, the product cores are individually contacted with the controllably heated obverse surfaces of the converging gelatin films 36 and 37. The films are stretched around the opposite sides of the cores symmetrically relative to apparatus center plane 54, thereby to define the applied layers 13 and 14 of the coating 12 of the desired product. The gelatin films are sealed to each other along the seam line 15 of the product and the thus conjoined and adhered films are cut to allow the gelatin enrobed products (shown as articles 60 in FIG. 13) to separate from a perforated gelatin web 61 which emerges from between dies 38 and 39. Web 61 is formed by the adherence of gelatin films 36 and 37 to each other by the dies. After emerging from between the dies, the web passes between a pair of driven mangle rolls 63 which have surface speeds slightly greater than the surface speeds of dies 38 and 39 so that web 61 is stretched between the dies and the mangle rolls. This stretching of the web enables the gelatin enrobed product cores, i.e., products 60, to self-separate from the web and to move, with the assistance of product guides 64 (cooperating with the web between the dies and the mangle roles), into product receptacles 65 where the products are collected before undergoing such further processing as may be necessary. Further processing steps may include washing of products 60 to remove any residues of lubricant applied to the gelatin films in baths 50, final drying, or perhaps application of timed release or enteric release coatings as appropriate. The web 61 emerging from mangle rolls 63 is collected in a receptacle 66.

FIG. 14 generally illustrates a preferred core feeding mechanism 40 useful with and as a part of the equipment shown in FIG. 13. Feeding mechanism 40 includes a first stage core feeder 67, an intermediate feeder 68, and a final feeder 69 of which core feed horn 56 is a component. The intermediate feeder and most of the structure of final feeder 69 are located in an enclosure 78 which has an inlet opening 76 in its top. First stage core feeder 67 includes a hopper 70, preferably having a closable cover 71, into which large quantities of cores for products to be film enrobed are introduced. Hopper 70 discharges cores

therefrom to intermediate feeder 68 via a discharge 72 from the hopper. The hopper is secured to a support 73. A vibrator 74 is connected to the bottom of hopper 70 to agitate cores in the hopper so that cores emerge as desired from hopper discharge 72 to pass through opening 76 in the top of enclosure 78. Where the products produced are to be film enrobed medicine tablets and the like in which it is desired that the applied film coating on each tablet tightly adhere to the tablet surfaces, it has been found to be important that the tablets, when finally introduced to contact with gelatin films 36 and 37, are as free of excessive dust particles as possible. The presence of dust particles on the tablet cores or on the obverse surfaces of the gelatin films applied around the tablet cores can result in imperfect sealing of the applied gelatin layers 13 and 14 to each other. Therefore, dedusting procedures are practiced in association with the intermediate and final stages of core feed mechanism 40.

The discharge 72 of hopper 70 leads to an inlet 76 below which is an open top intermediate feeder box 77 movably mounted in the upper portion of a dust-containment enclosure 78. The principal function of intermediate feeder 68 is to load individual product cores into a plurality of core downtubes 79 which connect to respective vertically disposed core passages 80 formed within core feed horn 56. Such loading of cores from box 77 to downtubes 79 is achieved by laterally shaking or vibrating box 77; this is accomplished by coupling the box to a stationary support bracket 81 via a suitable shaker drive device 83. The support bracket is inside enclosure 78 which is, in turn, mounted in any convenient way to a foundation 82. Preferably, the amplitude of oscillation of box 77 is greater than the amplitude of oscillation of the bottom of hopper 70. The upper ends of core downtubes 79 connect to the bottom of box 77 via suitable openings 85 as shown in FIG. 18. Dust either introduced to the interior of box 77 with the cores or generated within the box by agitation of the product cores is extracted from the interior of enclosure 78 through a duct 88 which is connected to a suitable source of vacuum.

Downtubes 79 are located within enclosure 78. Since box 77 is oscillated laterally relative to enclosure 78, downtubes 79 are flexible. The upper ends of the flexible downtubes connect to the bottom wall of box 77 around respective ones of openings 85.

The presently preferred form of downtube 79 is a length of tubular, helically wound spring, the inner diameter of which is sufficiently large to enable cores such as caplets to move readily along the lengths of the downtubes and into respective ones of passages 80 to which the lower ends of the downtubes are coupled. To facilitate dedusting of cores moving through downtubes 79, the helical springs used to define the downtubes are not tightly wound but rather, as shown in FIGS. 17 and 18, are defined with slight spacing between adjacent turns of the spring helix. It is preferred that at least the inner surfaces of each downtube be coated with a material having a low coefficient of friction, such as tetraflouroethylene.

It has been found that caplets, because of their geometry, feed best from box 77 to downtubes 79 when the openings 85 through the bottom of box 77 to the respective downtube are conically flared, concave upwardly, in the manner of a funnel as shown 87 in FIG. 18. It will be apparent that the size and geometry of the surfaces defining the openings

from box 77 to the respective core feed downtubes are defined as a function of the geometry of the cores which are to be handled.

In handling different cores, an objective may be to cause the seam line 15 between the applied gelatin layers of the finished enrobed cores to lie in either the major plane of symmetry 16 of the core or the secondary plane of symmetry 16' of the core. It has been found, particularly in the instance of caplet cores, that particular attention is to be given to the handling of the cores in the final core feeder to cause the cores to be properly aligned relative to the dies. Such alignment is important to the desired coincidence of seam line 15 with the core major plane of symmetry. It has been found that causing the core downtubes to be sloped, rather than vertical, over a portion of their lengths between the intermediate feeder and the top of core passages 80 significantly improves the probability that caplet cores will have proper alignment with the die cavities upon contacting the gelatin films as the caplet cores emerged from the lower ends of passages 80. It is preferred that a core alignment mechanism be incorporated into the core feed horn 56. Such a mechanism 90 is shown generally in FIGS. 14 and 15, in more detail in FIG. 16, and in greatest detail in FIG. 23. Mechanism 90, as illustrated, is arranged to cause cores introduced to the nip of dies 38 and 39 to have their major planes of symmetry 16 aligned with the die nip line so that the seam lines 15 between the applied film layers on the finished products lie substantially in the major plane of symmetry of the product cores. The principles of mechanism 90 can be used to provide a core alignment mechanism useful to cause tablet cores to have their secondary planes of symmetry 16' aligned with the die nip line.

An upper portion 91 (see FIG. 23) of each core passage 80 in core feed horn 56 has a circularly cylindrical configuration. A lower portion 92 of each passage has a cross-sectional configuration which the same shape as, and is slightly larger in dimension than the cross-sectional configuration of the core of interest. The configuration of the passage lower portion is oriented in horn 56 so a core in that passage portion is aligned with its major plane of symmetry parallel to and midway between the axes of rotation of dies 38 and 39. The location of the transition between the circular and core-contoured portions of the length of each passage 80 is at a common height along the lengths of the passages. As shown in FIGS. 16 and 23, the outer side surfaces of the feed horn which are disposed parallel to the axes of rotation of the adjacent dies are recessed 93 such that the vertical base surface 94 of each recess intersects the circularly cylindrical upper portion 91 of each core passage 80. However, the recess depths are defined so that the plane of surface 94 of each recess lies outwardly of the core-contoured lower portion 92 of each passage 80. That is, the elongate recess 93 formed in each side surface of core feed horn 56 intersects the lowermost portion of the circularly cylindrical upper portion 91 of each passage 80, but it does not have a depth sufficient to extend to the adjacent wall of the core-contoured lower portion 92 of each passage.

A belt 95, which preferably is defined by a suitably sized rubber O-ring, is engaged between a pair of support pulleys 96 disposed one adjacent each of the opposite ends of the core feed horn in the plane of recesses 93. The opposite parallel legs 98 and 99 of the belt

loop are disposed in recesses 93 sufficiently close to the recess vertical surfaces 94 that they pass in chordlike manner across diametrically opposite parts of the lower portion of the circular upper part of each passage 80 and the spacing between the opposite belt loop legs is less than the width of caplet core 11, e.g. A shaft 100, to which one of pulleys 96 is mounted, is rotated in a desired direction by operation of a motor 101. During times when core feed mechanism 40 is operated, motor 101 is also operated. Accordingly, belt 95 has one of its legs 98 moving in one direction across one outer portion of the lower end of the circular part of each passage 80 and has its opposite parallel leg 99 moving in the opposite direction across an opposite outer portion of the same part of the same passage.

As shown in FIG. 23, if a caplet core 11 approaches the upper end of core portion 92 of passage 80 aligned transversely of the major dimension of the cross-sectional shape of the passage lower portion, it cannot enter the passage lower portion. However, as such a misaligned caplet core approaches the passage lower portion 91, it engages the oppositely moving legs 98, 99 of belt 95 and, because of the opposite directions of motion of the belt legs, is turned about its length in passage upper portion 91 until it is angularly positioned so that it can enter passage lower portion 92. As the caplet is turned in the circular part of passage 80 so that it can enter into the lower portion of the passage, it quickly disengages itself from contact between the oppositely moving belt legs and quickly passes between those belt legs into the passage lower portion. The dimensions of the passage lower portion are slightly larger than the cross-sectional dimensions of the caplet core so that the core can move freely under the bias of gravity and other influences downwardly through passage portion 91 while having its major plane of symmetry substantially coincident with the major plane of symmetry of the passage lower portion. When the caplet emerges from the lower end of passage 80 into contact with gelatin films 36 and 37, the major plane of symmetry of the core will lie substantially in the plane of symmetry 54 of the enrobing apparatus. As enrobed by the gelatin films, the caplet or other tablet core will have the seam line 15 between the layers of gelatin applied to it substantially coincident with the core major plane of symmetry 16. The core alignment mechanism operates so quickly in a tangential manner upon cores in passages 80 that the mechanism has no discernible effect upon the free movement of cores along the passages under the influence of gravity and the height and weight of the core column.

If the products 60 to be produced in the enrobing apparatus are to have their seam lines 15 between applied film layers 13 and 14 lying in the secondary planes of symmetry 16' of the cores, then a suitably defined different core alignment mechanism can be used. For example, in such a different mechanism, the passage lower portions 92 could have the same shape as shown in FIG. 23 Thus, film enrobed medicine tablets having seam lines 15 aligned with either the major 16 or secondary 16' planes of symmetry of the tablets can be provided as the products of this invention.

FIG. 16 also shows that, as preferred, a switch 104 can be mounted to the core feed horn in association with each passage 80 for blocking the passage at a desired location along its length. Preferably that location is below the location of the belt 95. The switches can

be bistable electrical or pneumatic devices which, when in one state, allow a plunger to extend sufficiently into the cooperating passage 80 to prevent the movement of cores through the passages, but which, when in the other state, cause the plunger to be withdrawn from the passage.

FIGS. 19 through 22 show details of the drum-like dies 38 and 39 which are used for producing the preferred product 10 of this invention. Dies 38 and 39 are essentially identical. Each die is arranged to be rotated about an axis. Die 39 is positively driven at a desired angular velocity, and die 38 is slaved to driven die 39 by gears (not shown) between the dies so that dies 38 and 39 rotate synchronously in opposite directions about their respective axes of rotation. Since dies 38 and 39 are identical, except to the extent described above, a description of die 39 shall constitute a description of both dies.

Die 39, as shown in FIG. 20, has a circularly cylindrical working surface 107 extending along the length of the die drum between its opposite ends. There are defined in working surface 107 a plurality of recesses 108 each of which cooperates with a corresponding recess in the other die for defining a corresponding cavity between the dies as they turn about their axes of rotation into and out of substantially matching coaction with each other. Since, as shown in FIG. 19, dies 38 and 39 are used to produce products 10 which have caplet cores, the planform configuration of each recess 108 in each die has a geometry which corresponds to the top plan view of product 10 as shown in FIG. 1 but is somewhat oversized in width, length and depth relative to such product. Even as enwrapped and enrobed between films 36 and 37 within each cavity formed by cooperating recesses, the preform and films within the cavity are loose within the cavity and do not bottom-out or otherwise significantly contact the bottom or sides of the recesses. Each recess 108, as formed in a die working surface 107, is surrounded by a raised rim 109, the end of which is spaced from the adjacent die working surface and which makes essentially direct contact with the corresponding feature of the adjacent die as the dies turn synchronously about their respective axes. The edges of each recess rim, both toward and away from the corresponding recess, are rounded to desired small radii of curvature.

Each rim 109 of a recess 108 for use with caplets 12 has parallel opposite sides 110 aligned with the circumference of die 39 and arcuately configured portions 111 at each of the opposite ends of cavity 108 (see FIG. 21). For reasons which are described more fully below, the rounded end portion 111 of each cavity rim 109 has a base curvature in which the radius of the arc of the rim is substantially equal to one-half the width of cavity 108 between straight rib portions 110. At the extreme ends of each recess 108, a more curved arcuate portion 112, having a smaller radius of curvature, is centered on the elongate center line of the recess. The more curved portion 112 of the peripheral rim around each recess provides a supplemental volume (relief) 113 at each end of the recess. The end of each recess rim 109 spaced away from die working surface 107 is a land surface in the die.

The supplemental volume at each end of a die recess can have a geometry different from that shown in FIG. 21, if desired. For example, the supplemental volume, when viewed along a line normal to the die working surface, can have a shape resembling a

rectangle wrapped around the principal contour of the recess end. The supplemental volume shape which is most effective may and likely will vary with the shape and dimension of the core with which the die recess cooperates in any given instance. The principal significance of the supplemental volumes in a die recess is to assure that, in cooperation with the size and shape of the relevant article preform being handled at any given time and the orientation of that preform relative to the recess, the area of film disposed over the recess within the recess rim, at the time the die moves in conjunction with the other die to close the recess around the preform, is an area which is sufficient, in connection with the thickness, composition and condition of that film, to accommodate stretching of the film in all directions, without rupture of the film, to fully cover the preform in conjunction with the action of the film overlying the matching recess in the other die.

As shown in FIG. 20, a plurality of rows of recesses 108 are provided circumferentially of die 39. The rows can be uniformly spaced from each other along the axial extent of the die. In each row, the recesses are spaced at uniform intervals around the circumference of the die with a preselected spacing "d" (see FIG. 21) between the outer portions of recess rims 109 along the line of each row of recesses. Distance "d" is a relatively small distance; it is as small as workable consistent with the functioning of lands 109 to seal films 36 and 37 around individual preforms and to cut the film-enrobed preforms, with their gelatin enrobing layers sealed to each other, from web 61. Distance "d" preferably is determined with reference to the thickness of the films passing between the dies.

As shown in FIG. 20, two rows of teeth 115 are raised from die working surface 107 circumferentially of the die at each end of the die. The teeth on one die do not intermesh with the corresponding teeth on the other die. Teeth 115 comprise traction tires on the ends of each die for gripping the respective gelatin film which has a width transversely of the film web greater than the axial length of the drum.

It is presently preferred that recesses 108 have their long dimensions aligned with the circumference of the dies rather than with the axial extent of the dies. This orientation of the recesses on the die working surfaces is consistent with the presently preferred end-wise feeding of caplets 12 to the nip between dies 38 and 39 in the manner shown most clearly in FIG. 19.

As seen from FIG. 19, caplets 12 are individually dispensed in a passive, unclocked, self-timed manner into simultaneous contact with the heated obverse surfaces of gelatin films 36 and 37 substantially at the nip between dies 38 and 39 where they cooperate most closely with each other. The caplets emerge one at a time from the lower end of a lower portion 92 of a core passage 80 in core feed horn 56; there is one passage 80 for each row of recesses around a die. Each passage 80 has its centerline defined to intersect the centerline of the corresponding two rows of recesses 108 in the adjacent dies 38 and 39. As stated above, passages 80 are aligned along the functional center plane 54 of the core enrobing apparatus. Passages 80 open to the die nip area through the substantially knife-edged lower end of the wedge-shaped lower portion of the core feed horn. In each passage 80, caplets

12 are disposed lengthwise in end-to-end relation to each other in a caplet column in which each caplet stands on the caplet below it in the passage. The caplets in the lower portion 92 of each passage 80 have their major planes of symmetry 16 aligned with apparatus center plane 54 for the reasons described above with reference to FIG. 23.

The frequency at which individual caplets 12 emerge from the lower end of each passage 80 is a frequency which is self-defined within the enrobing apparatus. There are several things which affect this unclocked dispensing of caplets and other tablet cores to films 36 and 37 and to the rotary dies. These factors include the composition of the gelatin material from which films 36 and 37 are cast, the thickness of films 36 and 37, film elasticity, film temperature at the point of contact of each core with the films between the lower extent of the feed horn and the die nip, the tension in films 36 and 37 across recesses 108 as the films are engaged by each core, the adhesiveness of the films to the dispensed cores, core mass and size, the number of cores in the column of cores in each core passage 80, and the rate of advance of films 36 and 37 past the lower tip of the core feed horn. These factors are interrelated to each other with greater or less degrees of directness.

Pertinent tension in the films is determined, among other ways, by the difference in surface velocities of the dies as compared to tractor rolls 52. The surface velocities of the dies are defined to be a selected slight amount greater than the surface velocities of the tractor rolls. Another factor affecting film tension is the temperature of the film. Film elasticity is interrelated to the film composition, the film thickness and the film temperature. The extent to which the film obverse surfaces adhere to the cores is a function, among other things, of the film surface temperature. For cores of given mass, size and shape, there can be too few or too many cores in the core column within passage 80 for the self-timing aspect of the core-to-film feed operation to be achieved satisfactorily. One of the factors which affects the unclocked, self-timed dispensing of cores to films 36 and 37 from passages 80 is the static head of cores in the passages. These various factors and their interrelationships are discussed more fully below.

Particularly in the instance of caplet cores, it has been found important to provide the supplemental volumes 13 at the ends of die recesses 108. Caplets are a difficult configuration of core in the context of the self-timed dispensing effect. Round cores, or cores which are more round than they are of caplet configuration, are more readily handled than caplets in the unclocked core dispensing arrangement shown in FIG. 19.

It has been found that, when the various factors and influences described above are properly observed in relation to each other, tablet cores, even cores of caplet configuration, can self-feed satisfactorily into contact with films 36 and 37 without positive injection of the cores to the films and without other metering procedures being observed. The lower end of the lowermost core in passage 80 effectively contacts films 36 and 37 at a location on the films where the films overlie die recesses positioned at about the position of recesses 108' illustrated in FIG. 19. The gelatin film obverse surfaces, being sticky by virtue of heat having been applied to the films from heating blocks 57, grab a core from the lower end of passage 80 and carry the grabbed core with the films away from the lower end of the core

feed horn. As this occurs, the films stretch around the grabbed core within the corresponding recesses and, particularly where the presently preferred gelatin formulation described above is used, conform closely to the contours of the grabbed core and adhere to the core. Because each core is introduced into contact with the films with the major plane of symmetry of the core aligned with apparatus center plane 54, the films apply themselves to the core symmetrically about the core major center plane 16 and form a seam line 15 around the core at a location on the core which is essentially coincident with that major plane of symmetry. All of these things occur as the dies continue to rotate following first contact of each core with films 36 and 37. As a core enrobed between the gelatin films reaches and passes through the point of closest contact of the dies with each other, the films surrounding each core are sealed tightly together. Such sealing occurs due to the self-adhesive nature of the films. Essentially concurrently with sealing of the films tightly together thereby to define web 61, the lands defined by the ribs 109 which surround each cavity 108 move into sufficient proximity to each other to cut the enrobed cores from the web. At that point, products according to this invention are essentially complete save for such washing and further drying operations, and perhaps further coating operations, as may be desired.

The thickness of films 36 and 37 is a factor, among others, which affects the resiliency of the gelatin films during the core enrobing process. The stretchability of film over a core is also affected by film thickness. The minimum film thickness which can be used for successful enrobement of cores is in turn affected by the type of gelatin used to create films 36 and 37 and by the gelatin-liquid formulation. In rotary die core enrobement apparatus of the kind described above, it has been found that films having a thickness of from 0.02 to 0.04 inches thick worked well, although films having a thickness of 0.01 inch were handled successfully. For practical purposes, it is believed that gelatin films thinner than 0.005 will require the use of a specialized coating system. As noted above, if equipment of definition different from that described above is used, films of substantially greater thickness can be handled.

It has been found that the unclocked self-timed dispensing of stacked cores from passages 80 to soft elastic gelatin films engaged over and between rotary dies of the kind described above is relatively unaffected by die velocity. Surface speed of the dies should not be so high as to exceed the ability of the cores in passage 80 to move under the bias of gravity into contact with the films passing the lower end of the core feed horn at a frequency which corresponds to the effective frequency at which recesses 108 pass the same place.

It has been found, particularly in the instance of caplet cores, that close spacing between adjacent recesses 108 in each line of recesses circumferentially of the dies, and the provision of supplemental volumes 113 in the ends of the die recesses, are significant to eliminate the tendency of the die structure between adjacent recesses from nipping at the lower ends of cores fed to films 36 and 37 through passages 80.

It has been found that the temperature of the gelatin films as they pass the lower end of the core feed horn is significant to the fluidity of the gelatin film and its ability to form a seal around cores dispensed to the films. The precise temperature which is best in any

instance depends upon film thickness and the gelatin formula. Film temperature at and near the die nip is also affected by the geometry of the core feed mechanism in cooperation with the dies, and by how far from the die nip location the film heater blocks are located.

From experience with various gelatin formulations and film thicknesses, it has been found that the core feed wedge temperature is best controlled and maintained within a range of from 100° F. to 190° F. The precise temperature which is best used in any given instance depends upon the gelatin formula and film thickness. Temperature should be controlled within plus or minus 2° F. for optimum film sealing results.

Gelatin type, source, and formula have an impact upon film elasticity, the ability of the films to adhere to cores dispensed to the films, and the adhesion of the films to the dies. Gelatins with bloom values of from 150 to 180 are preferred, but it has been found that gelatins having a bloom value in the range of from 120 to 250 can be handled. Specific gelatins with blooms as high as 300 and as low as 100 can be custom manufactured.

The adhesion of the gelatin film to the product core is significant in two ways. In one way, adhesion of the film to a core produces a grabbing effect of the films upon the core to self-time the dispensing of cores onto the films. The other aspect of film adhesion is relevant during the product drying process where the applied gelatin layers forming the gelatin coating around the enrobed product becomes an integral part of the finished product and cannot, as presently preferred, be physically removed without damaging the core. This is particularly important where the product to be produced is a tamper-evident medicine tablet. It has been found that where the ratio of plasticizer to gelatin in the initial gelatin formulation is about 1:5, a very satisfactory tamper-evident gelatin film enrobed tablet is produced. Gelatin films cast from gelatin formulations having gelatin to plasticizer ratios in the range of from 3-1/3:1 to 15:1 will adhere to most tablet cores. Low ratios of plasticizer to gelatin result in a brittle coating around the tablet core, while high ratios result in a gelatin coating around the tablet which is flexible and can be peeled from the tablet.

It has been found that substantially any gelatin formulation which can be used successfully in the manufacture of soft elastic gelatin capsules containing flowable materials such as powder, liquids or pastes, can be handled in the processes and apparatus of this invention to produce applied-film gelatin coatings around a wide range of cores or product preforms. In that context, gelatin formulations having by-weight compositions of 32 percent to 50 percent gelatin, 17 percent to 35 percent plasticizer, 29 percent to 44 percent water, and colorants and pigments in the range of from 0.1 percent to 3 percent can be handled. However, if a gelatin coating which adheres to the product core is desired, then gelatin formulations having by-weight compositions of 40 percent to 60 percent gelatin, 5 percent to 12 percent plasticizer, 35 percent to 50 percent water, and colorants and pigments in the range of 0.1 percent to 3 percent should be considered. Glycerin and sorbitol can be used as single plasticizers or in combination with each other. In addition, other sugars and poly-hydroxy compounds can be used as additives and plasticizers. If a tamper-evident gelatin-coated medicine tablet is the desired end product, then the ratio of plasticizer to gelatin in the gelatin formulation should be in the range of about 1:5. It will be appreciated that the

range and versatility of gelatin film formulations which can be handled by the present technology makes possible the manufacture of gelatin coated tablets or other products which have peelable coatings, as where the applied-film coating is desired around the product core to serve as a protectant or preservative for the core.

The present invention provides significant advantages over previously known techniques for gelatin coating medicine tablets and the like by dipping processes. In order for dipping processes to be practiced, the gelatin baths into which tablets and the like are dipped must be in a liquid state. That means that such gelatin baths must contain substantial unbound water which is free to react with the active or other ingredients in the medicine tablets. In the practice of the present invention, on the other hand, substantially dry gelatin films exhibiting substantially low water activity are used to produce the desired gelatin coating around the medicine tablet core. In these gelatin films, the water molecules are significantly more bound to the other constituents of the film. The result is that there are few water molecules in the fluid which are free to react with the cores around which the films are applied. Also, applied gelatin films used in the practice of this invention are substantially cooler when they come into contact with medicine tablet cores than is the case of tablets dipped in gelatin baths which must be at relatively high temperature. Further, this invention can provide products in which there is no air trapped between the applied gelatin coatings and the cores to oxidize the core or any of its constituents.

While the presently preferred procedures and equipment have been described above with reference to FIGS. 13-23, other procedures and equipment can be used. As shown in FIG. 24, in apparatus 120 a pair of suitably formulated films 121 and 122 of desired thickness can pass from suitable film casting devices or other film sources (not shown) around respective rotary dies 123 and 124 to a nip 125 between the dies past a film heater 126 which cooperates with the films as they wrap around the dies. At least die 124, or both dies if desired, defines recesses 127 in its circumferential working surface shaped and sized to cooperate in the manner already described with desired article preforms such as medicine caplets. FIG. 24 shows that recesses 127 can be elongated along the axis of the die to cooperate with caplets dispensed lengthwise relative to the dies. A preform dispenser 128 is associated with one of the films, e.g. film 122, near heater 126 on the side of the heater opposite from die nip 125, for dispensing preforms in a desired positional attitude which corresponds to the manner in which the die recesses are formed. A film heater 129 is located ahead of the dispenser along the film to which preform dispensing occurs for heating the film before dispensing to a condition of sufficient surface tack that each dispensed preform adheres to the film to move with the film toward die nip 125.

Dispenser 128 comprises a plurality of preform magazines 130, one magazine for each row of recesses circumferentially of the die or dies. The magazines meter preforms to respective recesses in a preform transfer device 131 which in turn moves individual preforms to the adjacent film surface and places the preforms on the film surface at places on the film which correspond to respective die recesses. The film surface tack grabs the dispensed preforms and carries them with it under heater 126 which can also serve as a guide to hold

the dispensed preforms on the film without altering the places occupied on the film by the preforms. The operation of dispenser 128 is synchronized to movement of the films and the dies by a suitable actuating mechanism, such as a timing belt 132 which cooperates between the transfer device and a roller 133 which rotates in synchronism with movement of one of the films.

An apparatus of the kind shown in FIG. 24 can operate in the die area in different ones of several ways, depending upon the nature of the preforms, the precise nature of the film enrobement of preforms which is desired, and other factors. If both dies 123 and 124 define recesses 127, the dies can cooperate in the same manner as dies 38 and 39 to produce enrobed products like or similar to those shown in FIGS. 1-12. If only one die defines recesses 127 and the other die does not, then the dies can cooperate to produce film enrobed products in which the applied film coating on each preform has the applied layers disposed asymmetrically about the preform.

Alternatively, an apparatus 135 (see FIG. 25) for making applied-film enrobed products moves a pair of films 136 and 137 around and between a pair of rotary dies 138 and 139 which have surface recesses 140 of desired size, shape and orientation at corresponding places on their outer surfaces. A film heater 141 cooperates between the dies with the films wrapped on the dies to heat the films for the reasons already described.

Die 139 is hollow and is evacuated inside its circumferential shell in which recesses 140 are formed; those recesses communicate to the interior of the shell. A stationary vacuum barrier 143 cooperates with inner surfaces of the die shell over a desired major portion of the circumference of the shell but not over a selected arc 144 of the shell which is partially overlaid by the adjacent upper part of the wedge of heater 141. Arc 144 is substantially within the part of the surface of die 139 with which film 137 has contact. As the die shell rotates around the vacuum barrier, only those recesses subtended by arc 144 are exposed to the vacuum in the die. That vacuum acts upon those exposed die recesses to evacuate them, thereby to draw the portions of film 137 over those recesses into the recesses to form cups or depression in film 137. Film 137 is not subject to vacuum in the die as it reaches the lower portion of the heater wedge and approaches die nip 145.

Preforms 146 are fed to and into the vacuum-formed depressions in film 137, one to each depression, by a suitable preform feeder 147 as the depressions are formed in the film and before they pass under heater 141; the heater thereafter holds the preforms in the recesses of die 139 after the vacuum is released by barrier 143 from the adjacent film areas and until the preforms move into contact with film 136 near die nip 145. As each preform is moved into contact between both of films 136 and 137, it is enrobed by the films by coaction of the dies in the manner described above. A perforated film web 148 emerges from between dies 138 and 139.

In machinery arrangements 120 and 135, the preforms can be handled, if desired, so that they have predetermined positions relative to the dies as they are enrobed by the films so that the seam lines between the film layers applied to the preforms have controlled positions on the preforms.

Machinery arrangements 120 and 135 use dispensation of product preforms in a clocked manner (i.e., in a manner in which each dispensation event is actively timed to the position of a selected component of the machinery via a mechanical linkage between that component and the preform feeding and dispensing mechanism) to one of the moving films at a location substantially spaced from the location where the preforms are enrobed between the films. Clocked feeding of preforms into simultaneous contact with the two films adjacent the place of enrobing die coaction can also be used in the practice of this invention if desired, such as by an arrangement 150 of the kind shown in FIG. 26. Upon comparison of FIGS. 19 and 26, the similarities of machinery arrangement 150 to the presently preferred arrangement described above will be apparent, as will the differences between them.

As shown in FIG. 26, a pair of films 151 and 152 of suitable thickness, composition and condition move along respective film paths ,which converge at a nip 153 between coacting rotary dies 154 and 155. The dies have working surfaces which are contoured to define plural recesses 156 sized, shaped and spaced in the dies to cooperate with round medicine tablets 31 of the configuration shown in FIGS. 7 and 9, essentially as described above. Tablets 31 are fed, one at a time for each row of recesses in the two dies, into simultaneous contact with films 151 and 152 overlying corresponding pairs of die recesses through a passage 157, which can be vertically disposed, in a core feeder 158. Feeder 158 generally resembles feeder 40 described above in that it has a wedge-shaped heated lower portion 159 positioned symmetrically between dies 154 and 155 above die nip 153. The tablets to be dispensed are stacked in passage 157, preferably all with their major planes of symmetry in a desired plane relative to the die nip line, and the stack extends above a core drive device 160.

Core drive device 160 can be comprised of an eccentric cam 162 mounted on a drive shaft 163 which is so positioned adjacent passage 157 in combination with the cam contour that the cam extends into passage 157 through an opening 164 in the passage roll to contact a tablet in the passage. The cam contour is defined in combination with the rate of rotation of shaft 163 to engage a tablet in the passage each time a pair of recesses 156 reach desired positions at the lower end of the passage and to drive the tablet stack below the engaged tablet a desired distance downwardly in the passage. That distance is defined to be sufficient to move the lowermost tablet in the passage out of the passage enough to be simultaneously contacted by the films adequately to cause the films to securely grab that tablet and carry it with them with the dies and to be enrobed by and sealed between the films in the manner described above. The mechanism (not shown) for rotating shaft 163 is interrelated in a desired manner to the mechanisms for moving the films along their paths. Thus, the feeding of tablets 31 to films 151 and 152 is actively clocked rather than passively self-timed. A resilient element 166 can be carried in a wall of passage 157 very close to the passage open lower end to hold in the passage the tablet just above the one ejected from the passage by operation of cam 162. On the next operation of the cam, the tablet held by the resilient element is driven past the element and out of the passage.

A core feeding arrangement of the kind shown in FIG. 26 can be used to advantage in the practice of this invention where factors such as the size, shape, mass, and number of product cores in passage 157, in combination with other factors such as film thickness, film composition, film elasticity, film surface tack, die velocity, die recess configuration, and die recess spacing, among other factors, do not interrelate sufficiently well to enable the self-timed preform feeding effect described above to be used. For example, such an arrangement can be used where the product preforms are small light tablets.

In the case of other applications of the technology provided by this invention, the applied-layer coating may not conform precisely to the thing enrobed, so that the coating generally conforms to the contour of the thing coated, and the coating may not be bonded or adhered to the thing coated. Other films which have been shown to be useful in this broader context include films defined principally by polyvinyl alcohol. Other films which are believed to be useful include films made from starches, modified starches, alginates, modified gelatin, acrylates, polyvinyl pyrrolidone, cellulose derivatives both esters and ethers, and polysiloxanes, among others.

Products so packaged are often displayed for sale on hooks or rods, rather than on shelves. Such packages are characterized by a substantial width of film-covered card extending in all directions in a common plane from the packaged articles(s).

In a product according to this invention, by contrast to blister packaged and shrinkwrap packaged products, the applied-film coating around the thing coated is a package which has essentially no flange extending away from the coated thing. Also, the packaging coating can be part of the product itself, as in the instance of the presently preferred gelatin coated caplet 10 described above, instead of a package to be discarded when the product is used. The applied films are effectively sealed together in edge-to-edge manner. It will be seen, therefore, that this invention provides a new kind of applied-film product package which is materially different from previously known product packages, including gelatin-dipped medicine tablets.

Workers skilled in the art to which this invention pertains will appreciate that the foregoing descriptions of presently preferred and other embodiments of various aspects of this invention are primarily illustrative and exemplary and are not an exhaustive catalog of all of the ways in which the invention can be embodied. Such workers will appreciate the modifications, variations and alterations can be made to the products, formulations, procedures, and apparatus which has been described without departing from the scope of this invention.

What is Claimed is:

1. A method of film enrobing article preforms such as medicine tablets and the like in which providing a pair of elastic, plastic and self-adhering films each having obverse and reverse surfaces, are moved along selected paths through a place of coaction of a pair of coacting dies where the film paths coincide and the film obverse surfaces contact each other, the dies having cooperating working surfaces contoured for formation between them upon coaction of the dies of at least one cavity sized and shaped for loosely receiving therein a single article preform, characterized by the steps of

A) substantially at the place of die coaction individually dispensing for each cavity formed between the dies an article preform into contact with the obverse surface of at least one of the films at each location on the at least one film which corresponds to the location of a cavity for movement of the dispensed preforms through the place of die coaction,

B) at the place of die coaction, stretching the films into contact with each other peripherally around the preforms to cause each preform to be enrobed by and between the films, and sealing the films to each other at lines peripherally around and contiguous to each preform, and

C) separating the enrobed preforms from the films essentially at said peripheral lines.

2. The method according to claim 1 characterized in that the films are formed of gelatin-base material.

3. The method according to claim 2 characterized in that the film material comprises gelatin in the range of 32 to 50% by weight, a plasticizer in the range of 17 to 35% by weight, and the balance water and colorants.

4. The method according to claim 2 characterized in that the film material comprises gelatin in the range of 60 to 48% by weight, a plasticizer in the range of from 5% to 12% by weight, colorants and pigments not in excess of 3% by weight, and water.

5. The method according to claim 4 characterized in that the film material comprises about 45% gelatin and about 9% plasticizer.

6. The method according to claim 2 characterized in that the films have a thickness in the range of from 0.005 to 0.04 inches.

7. The method according to claim 1 characterized by coloring one film differently from the other film.

8. The method according to claim 1 characterized by heating the obverse surface of at least one of the films at a location proximate the place of die coaction to a temperature in the range of from 100°F to 190°F.

9. The method according to claim 1 wherein the article preforms are unitary hard medicine tablets containing at least one active ingredient and which have a plane of symmetry, and characterized by dispensing the tablets in such manner that, upon enrobement of the tablets by the films between the dies, there is formed about each tablet a film seam line which is substantially coincident with the tablet plane of symmetry.

10. The method according to claim 9 characterized in that tablets are round.

11. The method according to claim 9 characterized in that the tablets are caplets and the plane of symmetry is parallel to the length of the caplets.

12. The method according to claim 11 characterized by dispensing the caplets with the length aligned with the path of movement of the film to which the caplets are dispensed.

13. The method according to claim 1 characterized by providing the dies as rotary dies rotatable about horizontal axes, and dispensing the preforms into contact with the films from above the place of die coaction along a substantially vertical line.

14. The method according to claim 13 characterized by defining the cavities substantially equally between the dies so that, for each cavity formed between coacting dies, substantially one half said volume is within one die and substantially one half said volume is within the other die, and forming the dies with a plurality of the half-cavity volumes in each die working surface aligned along a line circumferentially of the die and with each half volume spaced a selected small distance from each adjacent one thereof along the line about the die.

15. The method according to claim 14 characterized by disposing a selected plurality of preforms in a column thereof along the vertical line along which the preforms are free to move downwardly by gravity, and allowing the preforms to move freely along the line for movement of the lowermost preform in the column into contact with the films and for movement with the films.

16. The method according to claim 15 characterized by imposing on the films at the place of coaction between the dies a selected amount of tension in each film in the direction of each film path.

17. The method according to claim 13 characterized by performing the dispensing procedure in an internally clocked manner without actively timing movement of the preforms along the vertical with reference to die angular position.

18. A method of film enrobing article preforms such as medicine tablets and the like as articles of manufacture, in which a pair of elastic and plastic gelatin-base films, which are self-adhering to the other film when at a predetermined temperature and which have obverse and reverse surfaces, are moved at essentially equal velocities along selected paths around and between a pair of matching coacting cylindrical rotary dies between which the film obverse surfaces are adjacent each other, which dies are essentially identical and each defines along at least one circumferential line a plurality of closely and uniformly spaced cavities in a surface thereof cooperable with the other die, the method being characterized by the steps of

A) stretching the films over the die surfaces at and proximate a place of substantial coaction of the dies with each other,

B) at a location along the film paths proximate the place of die coaction, heating the obverse surface of the films to the predetermined temperature,

C) individually dispensing a complete article preform essentially at the place of die coaction into contact with the obverse surfaces of the stretched films at locations on the films which overlie corresponding ones of the die cavities for deformation of the films into the cavities around the preform and for transporting engagement of the preform by the films,

D) at the place of die coaction, forcefully contacting the films with each other peripherally around the preforms to cause each preform to be enrobed by and between the films, and sealing the films to each other peripherally around each preform, and

E) separating the enrobed preforms from the films to provide the articles of manufacture each of which comprises a single preform sealed within a coating of substantially uniform thickness comprised of two gelatin layers sealed together in substantially edge to edge relation.

19. The method according to claim 18 characterized by supplying preforms to the films as a column of preforms of selected height in a vertical passage opening substantially to the place of die coaction at a location between corresponding lines of die cavities, each preform in the passage being free to move along the passage under the bias of gravity and the weight of other preforms above it in the column, and selecting the film thickness, formulation, temperature, and tension and the preform column height in coordination with each other so that preforms self-dispense from the passage to simultaneous contact with the films in synchronism with movement of corresponding opposite die cavities into alignment with each other in response to rotation of the dies.

20. The method according to claim 19 in which the preforms are essentially identical and each of the preforms has associated with it a selected reference plane, and characterized by supplying each preform to the films with the preform reference plane disposed in a selected orientation relative to the films.

21. The method according to claim 20 characterized by acting upon the preforms in the passage to place each preform in the selected orientation.

22. A method of film enrobing article preforms, such as medicine tablets and the like, as articles of manufacture, characterized by the steps of :

drawing together under axial tension, and into surface-to-surface contact at a nip location, a pair of preformed films which are elastic, plastic and capable of adhering to each other,

engaging at least one of the films with an article preform at a location on the film which is closely adjacent the nip between the films and at which the at least one film is free to deform laterally around the preform in response to such engagement so that the preform is taken up and drawn by the converging films to the nip,

stretching the converging films at the nip around the preform and into contact with each along a line around the preform and substantially contiguous to it to enrobe the preform between the films,

sealing the films together along the line, and

separating the enrobed preform from the films essentially along the line,

whereby there results a flangeless article of manufacture comprised of the preform which is enrobed in a coating of the film material.

23. A process for enrobing an article preform such as a medicine tablet with a substantially solidified biocompatible polymer, the process being characterized by the steps of:

drawing together at least two sheets of a substantially solidified biocompatible polymer to form a nip between the converging sheets,

dispensing a complete article preform into the nip of the converging sheets, and

sealing the sheets of converging polymer about the dispensed preform to enrobe the preform at least partially in the sheets.

24. The process according to claim 23 further characterized in that the providing step of the process includes casting the sheet from a liquid mixture of gelatin, a plasticizer for gelatin, and water.

25. The process according to claim 24 further characterized by performing the casting and drawing steps continuously and concurrently.

26. The process according to claim 24 characterized by formulating the mixture to have a gelatin-to-plasticizer weight ratio in the range of from about 3:1 to about 15:1.

27. The process according to claim 23 further characterized by further solidifying the polymer on the preform after performance of the sealing step.

28. The process according to claim 23 further characterized by sealing the sheets so that they fully enrobe the preform and are sealed to each other at all locations along a line encircling the preform and lying contiguous to the preform, and separating the enrobed preform from the sheets essentially along such line.

29. A process for enrobing an article preform such as a medicine tablet with a substantially solidified polymer, in which at least two sheets of a substantially solidified polymer are drawn together to form a nip between the converging sheets, and a complete article preform is dispensed into the nip of the converging sheets, characterized by the steps of

sealing together the converging polymer sheets about the dispensing preform essentially along a line about and closely contiguous to the preform to enrobe the preform at least partially in the polymer, and

separating the enrobed preform essentially along said line from the sheets.

30. The process according to claim 29 characterized in that the sealing step includes conforming the sheets to the preform at substantially all locations on the surface of the preform.

31. The process according to claim 30 further characterized in that the sealing step includes sealing the sheets to each other at all locations along the line.

32. The process according to claim 31 further characterized in that the sealing step includes adhering the polymer to the preform at essentially all points on the surface of the preform.

33. The process according to claim 32 in which the preform is a medicine tablet having at least one plane of symmetry, and further characterized by performing the sealing step to cause the seal line to lie essentially in one of those planes.

34. The process according to claim 32 in which the preform is a medicine tablet which has an axis of symmetry, and further characterized by performing the sealing step to cause the seal line to lie essentially in a plane which includes the tablet axis of symmetry.

35. The process according to claim 29 further characterized in that the drawing step includes disposing the sheets under tension across cooperating die cavities which mate at the nip, and the sealing step includes deforming the tensioned sheets around the dispensed preform from opposite sides thereof at the nip.

36. The process according to claim 29 further characterized by providing the sheets of a gelatin-based material comprising gelatin in the range of from about 40 percent to about 60 percent by weight, a plasticizer in the range of from about 5 percent to about 12 percent by weight, the balance comprising water and such pigments and colorants as may be desired.

37. The process according to claim 29 further characterized in that providing the sheets of a gelatin-based material comprising gelatin and a plasticizer in which the gelatin-to-plasticizer weight ratio is in the range from about 3:1 to about 15:1.

38. The process according to claim 29 further characterized in that the dispensing step includes moving a preform into contact with at least one of the sheets and allowing the contacted preform to be grabbed by the sheet for movement into sheet deforming cooperation with the sheet.

39. The process according to claim 38 further characterized in that the preform moving step includes placing a stack of complete article preforms in contact at a lower end of the stack with the at least one of the converging sheets adjacent to the nip so that the bottom preform in the stack is grabbed and drawn into the nip by at least one sheet.

40. The process according to claim 38 further characterized by placing the stack so that the bottom preform in the stack contacts both of the converging sheets.

41. A process for enrobing an article preform such as a medicine tablet with a substantially solidified polymer, in which at least two sheets of a substantially solidified polymer are drawn together to form a nip between the converging sheets, characterized by the steps of

placing a stack of complete article preforms in contact at one end with at least one of the converging sheets adjacent to the nip so that the end preform of the stack in contact with a sheet is grabbed and drawn into the nip by at least one of the converging sheets, and

sealing the two converging polymer sheets about the grabbed and drawn preform to enrobe the preform at least partially in the sheets.

42. The process according to claim 41 further characterized in that there are two sheets of substantially solidified polymer, each of which is elastic, plastic and adherable to

the other sheet, and the drawing step includes creating a selected amount of tension in each sheet and disposing the tensioned sheets in surface-to-surface contact with respective dies which are moveable together at the nip to place the sheets in surface-to-surface contact and which cooperate at the nip to form a cavity sized and configured to loosely accommodate the preform therein, and placing the stack of preforms so that the end preform contacts the two tensioned converging sheets essentially simultaneously.

43. The process according to claim 42 further characterized by coordinating the drawing, sheet tensioning and preform stack placing operations so that the sheets grab the stack end preform at locations on the sheets which cause the grabbed preform to be placed between the sheets within the cavity.

44. The process according to claim 43 further characterized by performing the sealing operation to seal the sheets about the preform essentially along a line about and closely contiguous to the preform, and separating the enrobed preform from the sheets essentially along that line.

45. The process according to claim 43 in which the dies are configured for forming at the nip at different times respective one of a plurality of cavities each sized and configured to loosely accommodate a preform therein, and further characterized by forming the stack of preforms so that as the stack end preform is grabbed and drawn into the nip, the next preform in the stack moves to become stack end preform.

46. The process according to claim 41 further characterized by forming the stack of preforms for self-metering of the stack end preform into contact with the at least one sheet.

47. The process according to claim 41 further characterized by forcing the stack end preform into contact with the at least one sheet.

48. The process according to claim 41 further characterized in that the sealing step includes conforming and adhering the sheets to the grabbed preform.

49. The process according to claim 48 in which the preform is a medicine tablet and the polymer is gelatin, and further characterized by sealing the sheets together at all locations along a line about and closely contiguous to the preform.

50. The process according to claim 49 in which the tablet has a plane of symmetry, and further characterized by creating the stack of tablet preforms so that at least the stack end tablet has its plane of symmetry disposed essentially parallel to the nip, and sealing the sheets so that the seal line lies substantially in the tablet plane of symmetry.

51. The process according to claim 49 in which the tablet has an axis of symmetry, and further characterized by creating the stack of tablet preforms so that at least the stack end tablet has its axis of symmetry disposed normal to the nip, and sealing the sheets so that the seal line lies in a plane which includes the tablet axis of symmetry.

52. The process according to claim 41 in which the preform is a medicine tablet and the polymer is gelatin, and further characterized by forming the sheets from a mixture of gelatin and a plasticizer so that the formed sheets have a gelatin-to-plasticizer weight ratio in the range of from about 3:1 to about 15:1.

53. Apparatus for film enrobing article preforms of selected size and shape such as medicine tablets and the like, in which a pair of matching dies have coacting working surfaces configured to define between them, upon movement of the working surfaces into coacting relation at a selected place, at least one cavity of sufficient size and shape to receive loosely therein one of the article preforms, and two films of selected thickness and cosealable composition are moved along respective paths which converge at the place of coaction between the die working surfaces with the films in overlying relation to the respective cavity defining features of the die working surfaces, characterized by

means cooperating with the film paths for creating in films moving therealong to said place predetermined conditions of plasticity and axial tension in the films as disposed at said place in said overlying relation to the die working surfaces,

preform dispensing means located proximate the place of die coaction operable for presenting preforms individually to at least one of the films in a selected orientation of the dispensed preforms relative to the dies at respective film locations which correspond to the die cavities, the presented preforms moving with the at least one film to the place of die coaction for enrobing engagement there between the films within the die cavities, and

means for moving the dies into and out of coacting relation at said place, the dies being formed to cause them, when moving into coacting relation, to apply the films to the preforms from opposite directions, and to seal the layers of film so applied to the preforms to each other in essentially edge-to-edge manner.

54. Apparatus according to claim 53 in which the dies are cylindrical rotary dies which substantially register with each other along a line parallel to the die axes, the preform dispensing means is substantially centered on a plane which includes the die registration line, the cavity defining features in the die working surfaces include a plurality of recesses in each die at uniformly spaced locations along the respective line circumferentially of the dies, and further characterized by means for timing dispensing of a preform to the films to coincide with the presence of a corresponding pair of die recesses at a certain location relative to the die registration line.

55. Apparatus according to claim 54 further characterized in that the dispensing means includes a passage through which preforms can move and which opens at an end toward the die registration line substantially at said certain location, the passage being sufficiently long adjacent the end thereof that a plurality of preforms can be disposed in the passage in a row, and the timing means includes means periodically engageable with a preform at a selected place in a row thereof in synchronism with rotation of the dies for urging preforms in the passage between the selected places and the passage end to move toward the passage end.

56. Apparatus according to claim 54 further characterized in that the means for timing is a passive means.

57. Apparatus according to claim 54 further characterized in that the means for timing is sensitive, inter alia, to selected characteristics of the preforms and of the films at the certain location, the dispensing means includes a substantially vertical passage through which preforms can move and which opens toward the die registration line substantially at said certain point, the passage being sufficiently long to contain therein a selected minimum number of preforms stacked in a column, and the selected characteristics of the preforms include the mass of a preform and the number of preforms stacked in a column in the passage.

58. Apparatus according to claim 57 further characterized in that the selected characteristics of the films include their thickness, elasticity, tension, and their properties of adhesion to a preform.

59. Apparatus according to claim 57 further characterized in that the means for timing includes the spacing between adjacent recesses along the respective lines circumferentially of the respective dies.

60. Apparatus according to claim 57 further characterized in that the means for timing includes the configuration of the recesses in each of the dies.

61. Apparatus according to claim 54 in which the preforms are medicine tablets and the like each having a selected plane of symmetry, and further characterized in that the dispensing means includes aligning means for dispensing the tablets into contact with the films with the selected plane of symmetry of each tablet substantially coincident with the plane on which the dispensing means is centered, whereby the films connect at a seam line between the films substantially in the tablet selected plane of symmetry.

62. Apparatus according to claim 61 further characterized by a passage in the dispensing means opening to the films and through which the tablets can move toward the

films, and by means for turning in the passage to a position for contact in said plane-to-plane coincidence any tablets in the passage not disposed for such contact with the films.

63. Apparatus according to claim 62 further characterized in that the passage extends substantially vertically in the dispensing means from the opening and has a lower portion cross-sectionally contoured in conformance with a tablet having its major plane of symmetry coincident with center plane of the dispensing means, and there are tablet turning means in the passage above the lower portion thereof for engaging and turning tablets into alignment with the cross-sectional contour of the passage lower portion.

64. Apparatus according to claim 63 further characterized in that the dies define corresponding pluralities of circumferential lines of recesses for forming a corresponding plurality of cavities along the die registration line, the dispensing means defines a corresponding plurality of said passages, and the tablet turning means is an active means common to all of the passages.

65. Apparatus for film enrobing article preforms of selected size and shape such as medicine tablets and the like, in which a pair of rotary dies have coacting cylindrical working surfaces each defining along a circumferential line a uniformly and closely spaced plurality of recesses each of which is cooperable with a similar recess in the other die to form a cavity of sufficient size and shape to receive loosely therein at least one of the article preforms, and two films of selected thickness and composition are moved along respective paths which converge at a place of coaction of the dies at which the films are disposed in tension in overlying relation to the respective die recesses, and characterized by

film conditioning means cooperating with the film paths adjacent each die proximate the place of die coaction for creating in films moving therealong predetermined conditions of electricity, deformability, adhesivity and axial tension in the films as disposed at said place in overlying relation to the die recesses, and unclocked preform dispensing means located centrally between the dies substantially at the place of die coaction operable for dispensing preforms individually to essentially simultaneous contact with the films at film locations overlying corresponding die recesses so that each dispensed preform moves with the films into enrobing engagement between the films within a corresponding cavity.

66. Apparatus for enrobing a medicine tablet and the like with a layer of substantially solidified polymer, the apparatus being characterized by

means for drawing together at least two sheets of a substantially solidified polymer to form a nip between the converging sheets,

means for dispensing a tablet into the nip of the converging sheets,

means for sealing together the converging polymer sheets about the dispensed tablet essentially along a line about and closely contiguous to the tablet to enrobe the table in the polymer, and

means for separating the enrobed tablet essentially along said line from the sheets.

67. Apparatus according to claim 66 wherein the tablet has at least one plane of symmetry, and further characterized in that the dispensing means and the sealing means are cooperatively coordinated to cause the seal line between the sheets to lie essentially in one of those planes.

68. Apparatus according to claim 66 wherein the tablet has an axis of symmetry, and further characterized in that the dispensing means and the sealing means are cooperatively coordinated to cause the seal line between the sheets to lie essentially in a plane which includes the tablet axis of symmetry.

69. Apparatus according to claim 66 characterized in that the means for dispensing includes means for moving a tablet into contact with the two converging sheets and for allowing the contacted tablet to be grabbed by the sheets for movement with the sheets into cooperation with the sealing means.

70. Apparatus for film enrobing medicine tablets and the like and characterized by

means for drawing together under axial tension, and into surface-to-surface contact at a nip location, a pair of preformed films which are elastic, plastic and capable of adhering to each other,

means for engaging at least one of the films with a tablet to be enrobed at a location on the film which is closely adjacent the nip between the films and at which at least one film is free to deform laterally around the tablet in response to such engagement so that the tablet is taken up and drawn by the converging films to the nip,

means for stretching the converging films at the nip around the tablet and into contact with each other along a line around the tablet and substantially contiguous to it to enrobe the tablet between the films,

means for sealing the films together along the line, and

means for separating the enrobed tablet from the films essentially along the line.

71. An enrobed tablet having a tablet core within a coating of ingestible, substantially solidified polymer, the coating being characterized by two applied layers of preformed film of the polymer which are sealed together along and terminate at a line encircling the core and which conform to and tightly adhere to the core without openings in the coating.

72. An enrobed tablet according to claim 71 wherein the core is of caplet configuration which is substantially longer in one direction than in either of two other directions orthogonal to each other and to the one direction, and further characterized in that the seal line between the applied layers is disposed substantially in a plane parallel to the one direction.

73. An enrobed tablet according to claim 72 further characterized in that the caplet configuration includes a cylindrical surface which extends parallel to the elongated one direction between ends of the caplet and around the caplet ends, and the seal line is located on the cylindrical surface.

74. A gelatin enrobed tablet having a tablet core and a gelatin-based coating enrobing the core, the coating being characterized by two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the coating being comprised of gelatin and a plasticizer present in a weight ratio of from about 3:1 to about 15:1.

75. A tablet according to claim 74 further characterized in that the coating adheres sufficiently tightly and securely to the core that coating cannot mechanically be removed from the core without removal of a part of the core.

76. A tablet according to claim 74 further characterized in that the coating conforms and adheres to the core.

77. A tablet according to claim 76 further characterized in that the coating is hard in the finished tablet.

78. A tablet according to claim 77 further characterized in that the coating has no openings in it.

79. A gelatin enrobed tablet having a tablet core and a gelatin-based coating enrobing the core, the coating being characterized by two layers of preformed gelatin film which are sealed together along and terminate at a seam line encircling the core, the coating conforming to the core contours and having no openings in it.

80. A tablet according to claim 79 further characterized in that the coating tightly adheres to the core.

81. A tablet according to either of claims 70 and 80 characterized in that the seam line is substantially aligned with a plane of symmetry of the core.

82. A tablet according to claim either of claims 79 and 80 further characterized in that the seam line lies substantially in a plane which includes an axis of symmetry of the core.

83. A tablet according to claim 79 further characterized in that the core is of caplet configuration.

84. A tablet according to claim 79 further characterized in that the coating is comprised of gelatin and of a plasticizer present in a weight ratio in the range of from about 3:1 to about 15:1.

85. A gelatin enrobed tablet having a tablet core and a gelatin-based coating enrobing the core, the coating being characterized by two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the coating tightly adhering to the core and being hard in the finished tablet.

86. A tablet according to claim 85 further characterized in that the coating has no openings in it.

87. A tablet according to claim 85 further characterized in that the coating adheres sufficiently tightly and securely to the core that the coating cannot mechanically be removed from the core without removal of a part of the core.

88. A tablet according to claim 85 further characterized in that the coating is comprised of gelatin and of a plasticizer present in a weight ratio in the range of from about 3:1 to about 15:1.

89. A tablet according to claim 85 further characterized in that the seal line is substantially aligned with a plane of symmetry of the core.

90. A tablet according to claim 85 further characterized in that the seal line is substantially in a plane which includes an axis of symmetry of the core.

91. A tablet according to any one of claims 85 through 90 further characterized in that the core is of caplet configuration.

92. A gelatin enrobed tablet having a tablet core and a gelatin-based coating enrobing the core, the coating being characterized by two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the coating tightly adhering to the core and having its seal line substantially aligned with a plane of symmetry of the core.

93. A tablet according to claim 92 further characterized in that the coating has no opening in it.

94. A tablet according to claim 92 further characterized in that the coating adheres sufficiently tightly and securely to the core that the coating cannot mechanically be removed from the core without removal of a part of the core.

95. A tablet according to claim 92-94 further characterized in that the coating is comprised of gelatin and of a plasticizer present in a weight ratio of from about 3:1 to 15:1.

96. A tablet according to claim 95 further characterized in that the coating in the finished tablet is hard.

97. A gelatin enrobed tablet having a tablet core and a gelatin-based coating enrobing the core, the coating being characterized by of two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the coating tightly adhering to the core and having its seal line substantially in a plane which includes an axis of symmetry of the core.

98. A tablet according to claim 97 further characterized in that the coating has no openings in it.

99. A tablet according to claim 97 further characterized in that the coating adheres sufficiently tightly and securely to the core that the coating cannot mechanically be removed from the core without removal of a part of the core.

100. A tablet according to claim 97-99 further characterized in that the coating is comprised of gelatin and of a plasticizer in a weight ratio of from about 3:1 to 15:1.

101. A tablet according to claim 100 further characterized in that the coating in the finished tablet is hard.

102. A gelatin enrobed tablet having a tablet core and a gelatin-based coating enrobing the core, the coating being characterized by two layers of preformed gelatin film which are sealed together along and terminate at a line encircling the core, the coating adhering to the core sufficiently tightly and securely that coating cannot mechanically be removed from the core without removal of a part of the core.

103. A tablet according to claim 102 further characterized in that the coating has no openings in it.

104. A tablet according to claim 102 further characterized in that the seal line is substantially aligned with a plane of symmetry of the core.

105. A tablet according to claim 102 characterized in that the seal line is substantially in a plane which includes an axis of symmetry of the core.

106. A tablet according to either of claims 104 or 105 further characterized in that the core is of caplet configuration.

107. A gelatin composition castable into a film capable of being deformed around a medicine tablet and the like, of conforming to the surfaces of the table, of bonding to a second film of similar composition, and of curing to a tough coating around the tablet, the composition comprising gelatin and a plasticizer in a weight ratio of from about 3:1 to about 15:1, the balance being comprised of water and such pigments as may be desired.

108. A gelatin composition castable into a film which is capable of being deformed around a medicine tablet and the like, of conforming to and bonding to surfaces of the tablet, of bonding to a second film of similar composition, and of curing to a hard, glass-like coating on the tablet, the composition comprising gelatin in the range of from about 40 percent to about 60 percent by weight, a plasticizer in the range of from about 5 percent to about 12 percent by weight, the balance comprising water and such pigments and colorants as may be desired.

109. A composition according to claim 108 wherein the composition is comprised by weight of about 45% gelatin, about 9% glycerin as a plasticizer, pigments and colorants not in excess of about 3%, and water.

110. A gelatin composition according to claim 108 wherein the plasticizer is glycerin.

111. A gelatin composition according to claim 108 wherein the ratio of gelatin to plasticizer is in the vicinity of 5:1.

112. A composition castable into a film which is capable of being deformed around a medicine tablet and of bonding to a second film of similar composition, the composition comprising a plasticizer, a base compound, and a solvent compatible with the plasticizer and the base compound, the base compound being selected from the group consisting of gelatins, modified gelatins, starches, modified starches, alginates, acrylates, polyvinyl pyrolidone, polyvinyl alcohol, cellulose derivatives both esters and ethers, and polysiloxones.

113. A die useful with a similar cooperating die for enrobing between a pair of films of soft elastic and plastic material of selected thickness individual ones of a plurality of essentially identical medicine tablets and the like having specified overall geometry and size, which tablets are supplied toward a substantially linear place of coaction of the die with

its cooperating die along a path substantially normal to the place of die coaction and disposed substantially symmetrically between the dies, the die comprising a drum-like article rotatable in a selected direction about an axis and having a substantially circularly cylindrical outer working surface in which are formed at regularly spaced intervals along at least one line circumferentially about the working surface a plurality of essentially identical recesses each having an opening shaped geometrically similarly to the geometry of one of the tablets and dimensioned oversize relative to the tablet, each recess being bounded by a rim conforming to the shape of the recess opening.

114. A die according to claim 113 characterized in that the rim of each recess at least at a portion of the recess on the corresponding line of recesses toward the direction of die rotation being relieved a selected amount away from the center of the recess.

115. A die according to claim 114 further characterized in that the relief of each end of each recess is defined by a concavity in the rim and the adjacent recess surfaces.

116. A die according to claim 115 further characterized in that the rim concavity is arcuate and has an effective radius of curvature less than the adjacent rim portions.

117. A die according to Claim 116 wherein the tablets are of caplet configuration, and further characterized in that the die recesses on each line are elongated in a direction along the line.

118. A die according to claim 117 further characterized in that the spacing between each adjacent pair of recess rims along the corresponding line of recesses is as small as possible consistent with the thickness and material of the films with which the die cooperates in use.

119. In combination with a pair of dies each according to claim 118, a caplet feed mechanism for supplying toward the plane of die coaction principally under the bias of gravity a plurality of caplets stacked end-to-end in a column along the path, the caplets in the column at least at a lower end thereof having a predetermined orientation to the path, each die being operable for advancing a respective one of the films toward the place of die coaction in response to rotation of the die, the feed mechanism locating the column lower end between the films closely proximate the place of die coaction.

Fig. 1

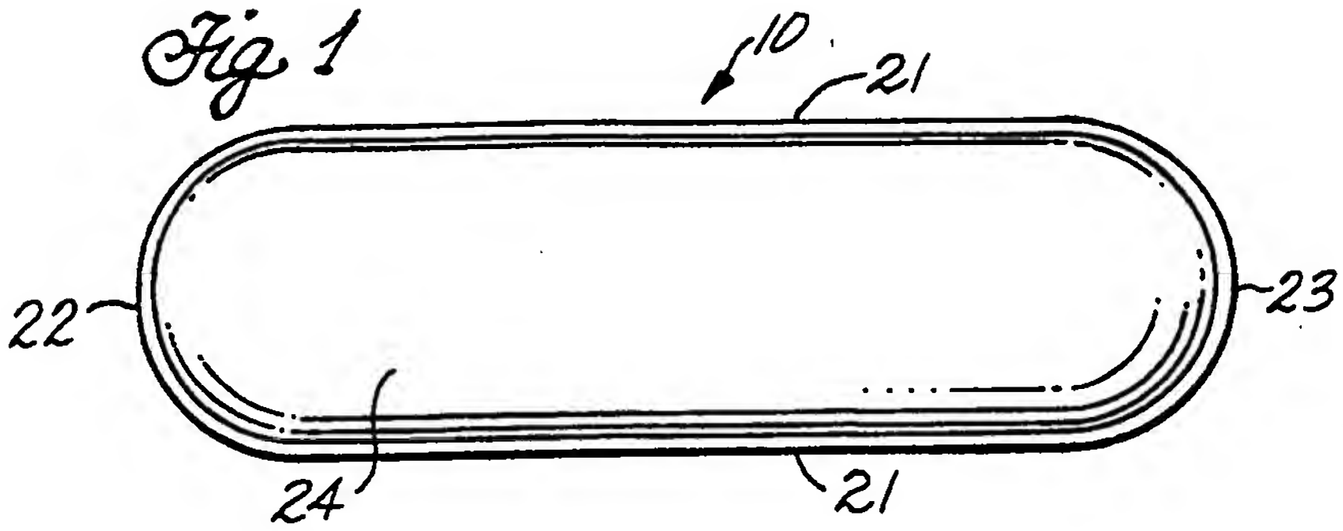


Fig 2

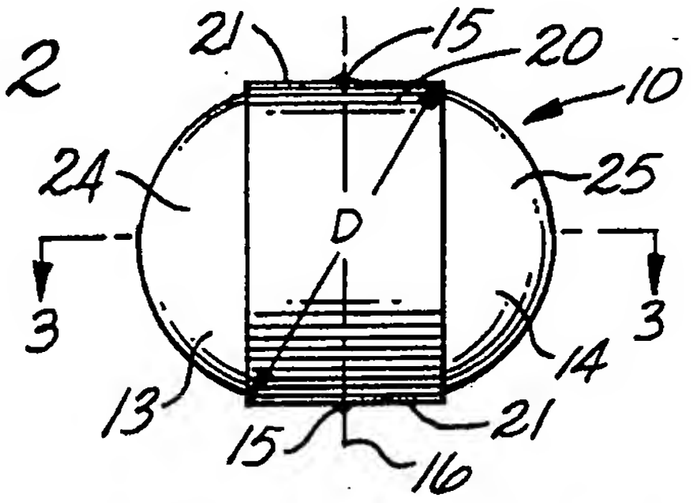


Fig 3

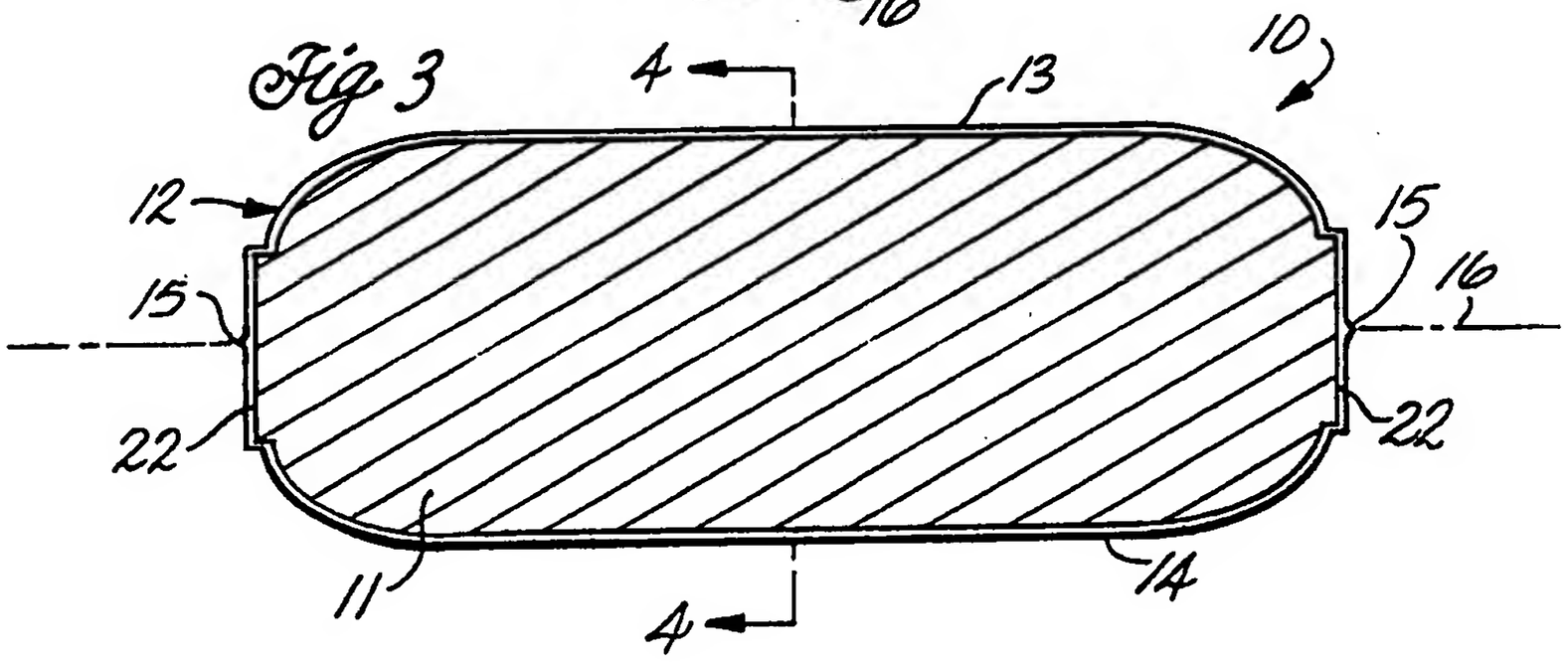


Fig 4

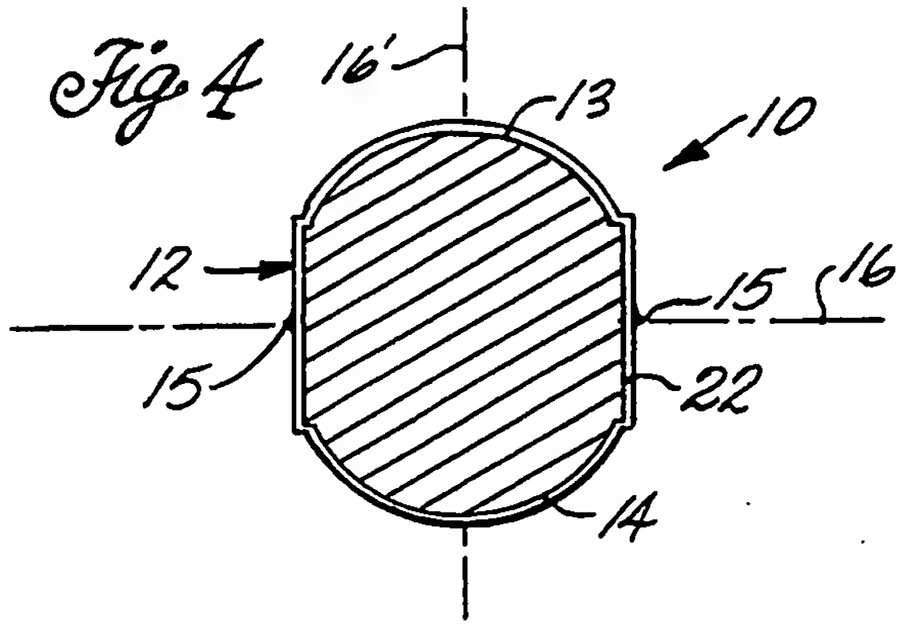
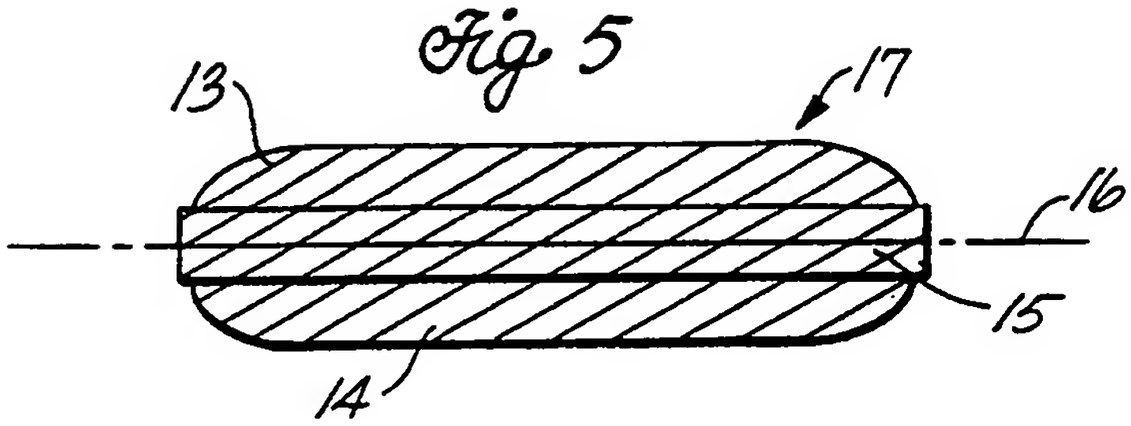


Fig 5



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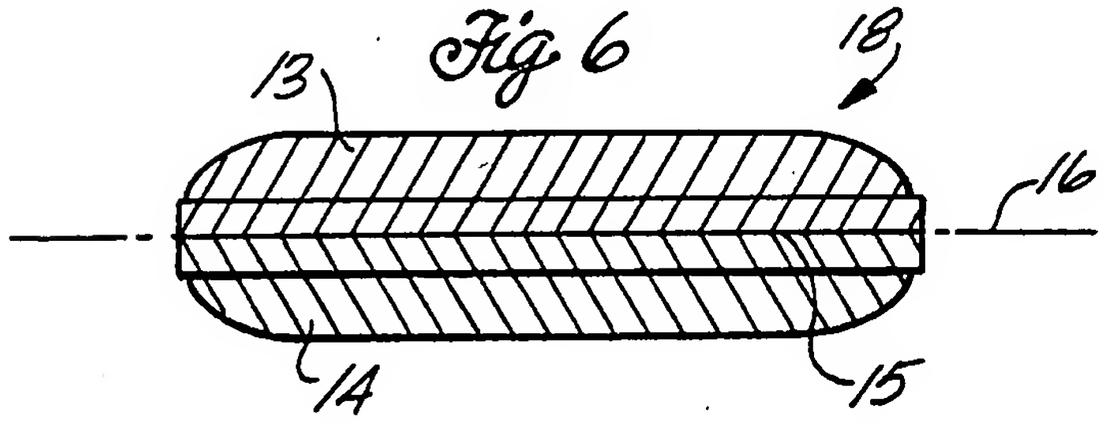

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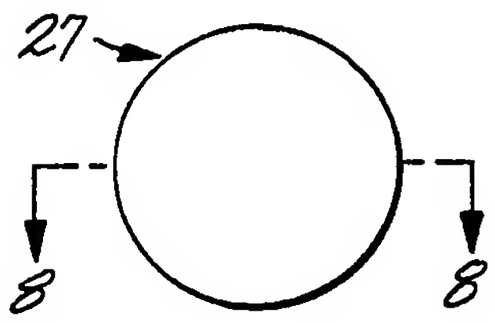

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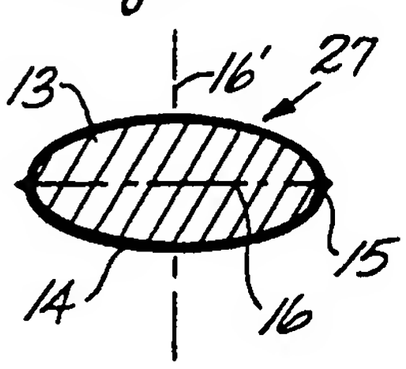

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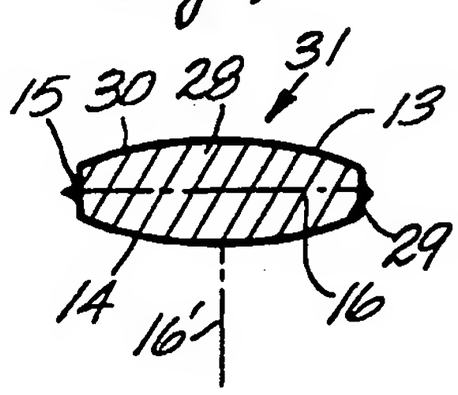

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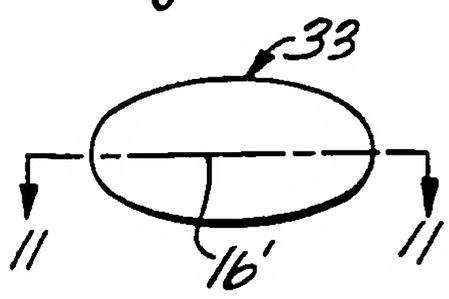

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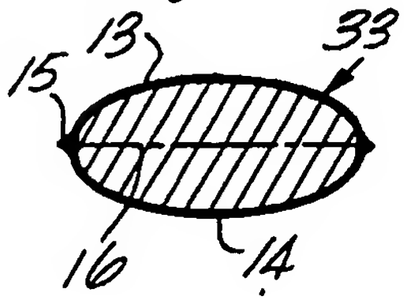

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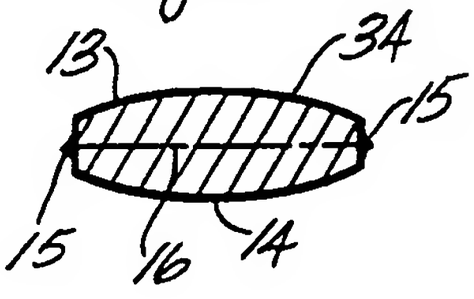

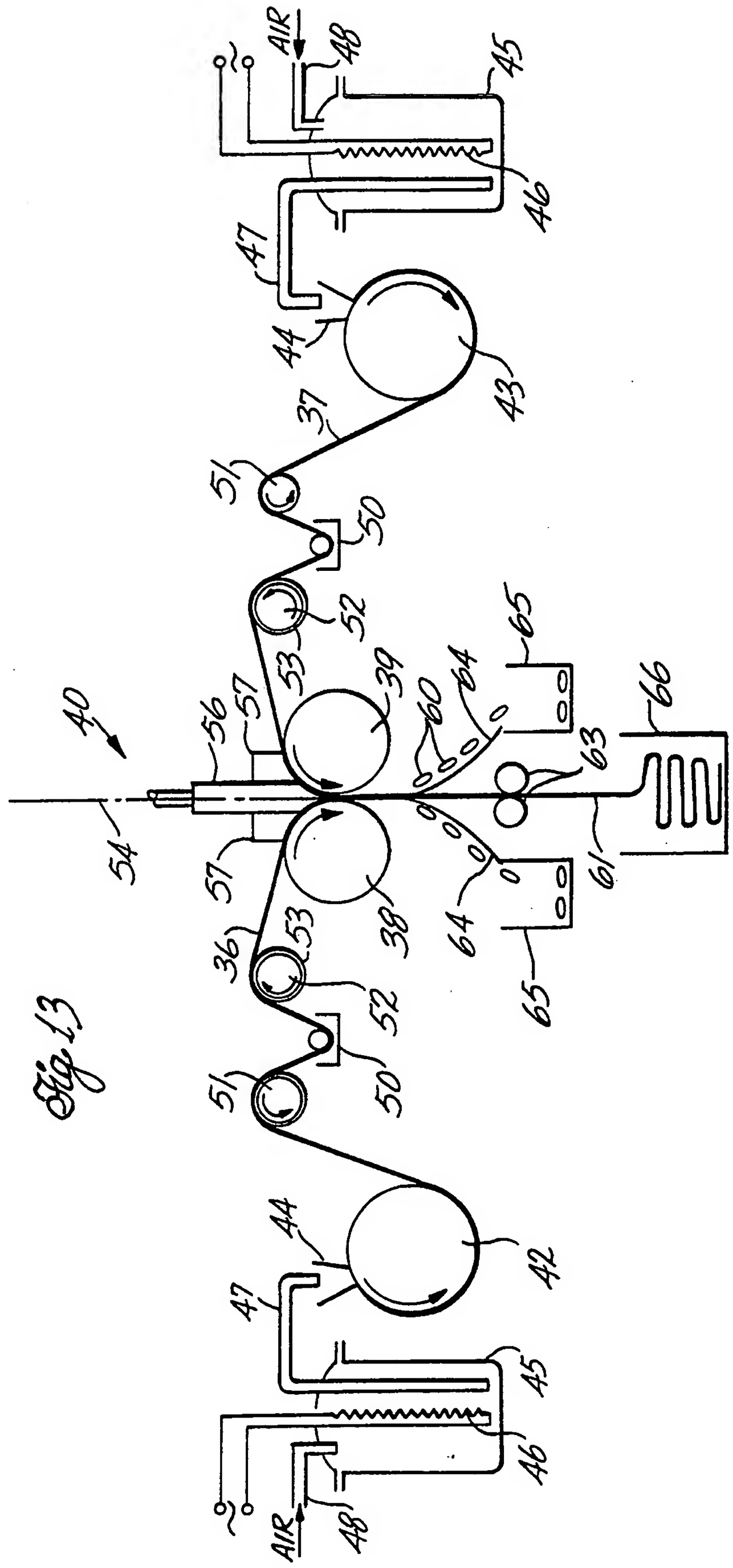
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Fig 13

Fig. 14

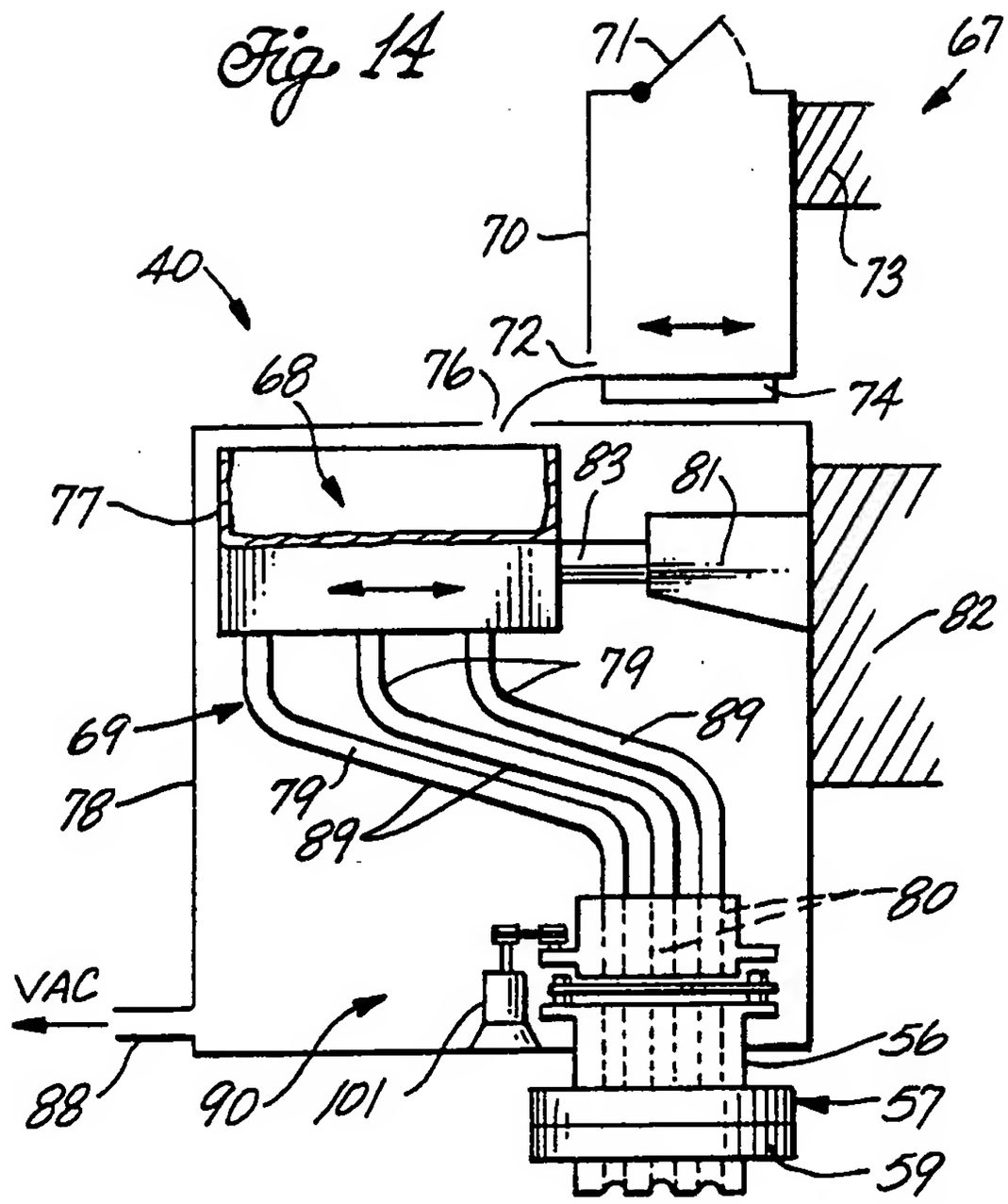
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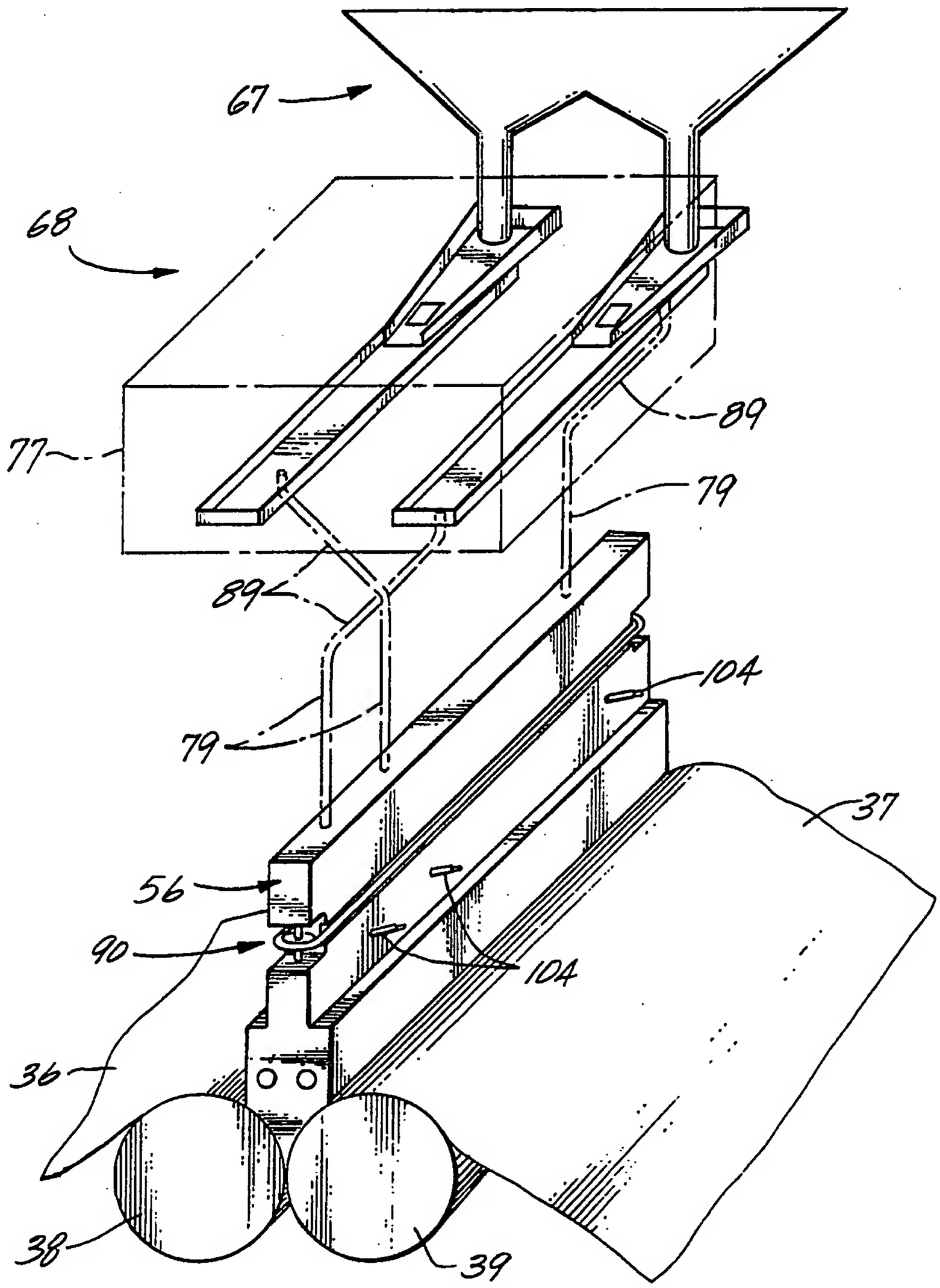
Fig. 15



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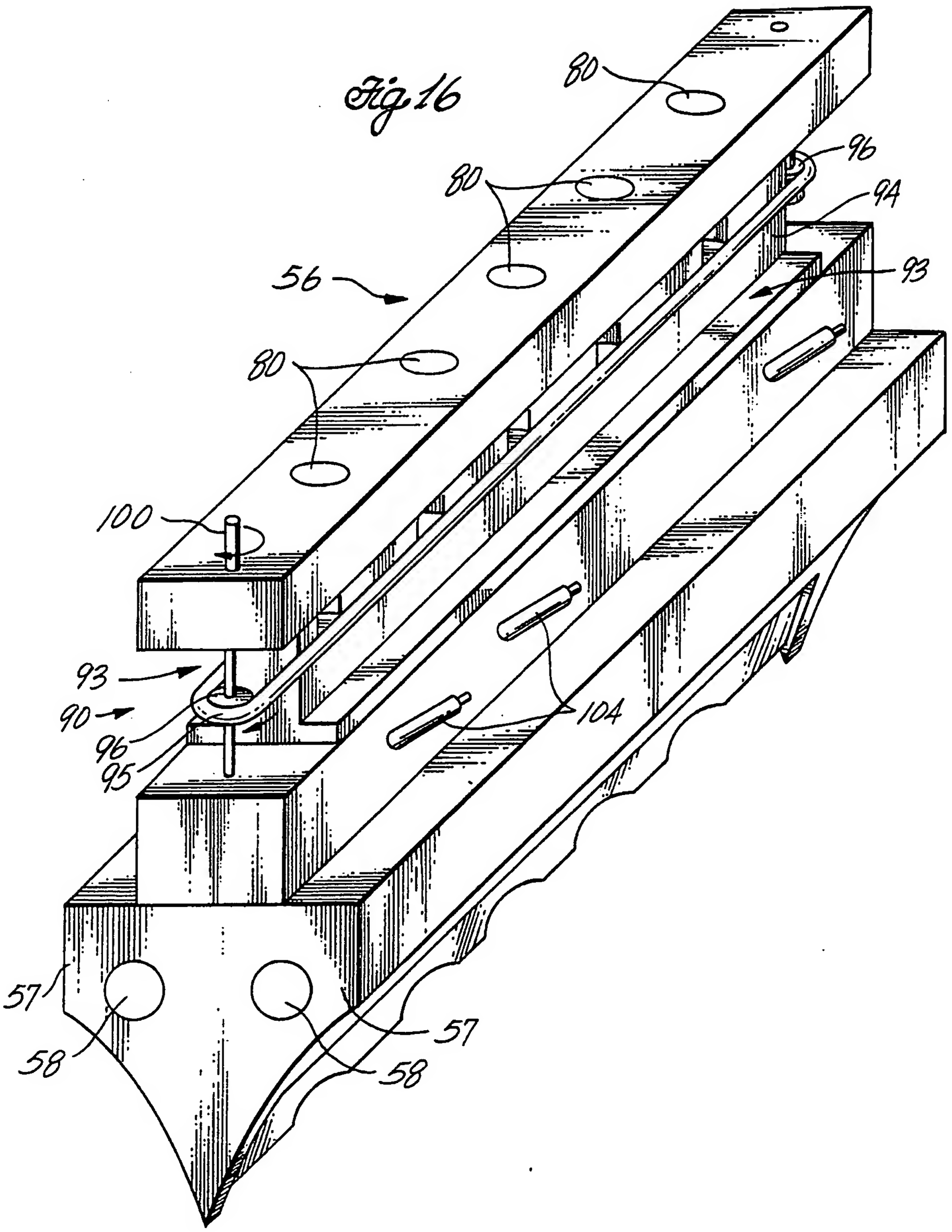

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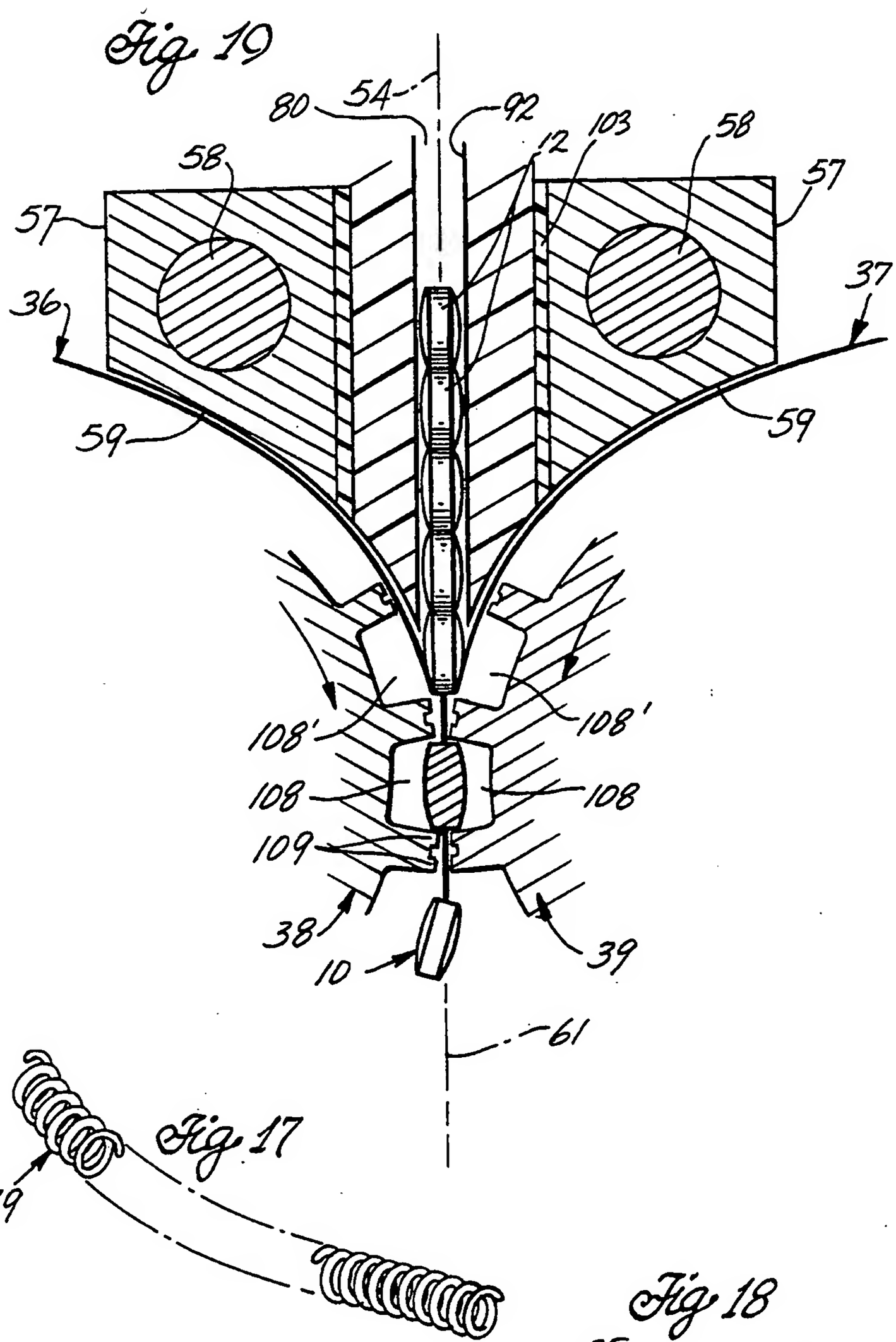
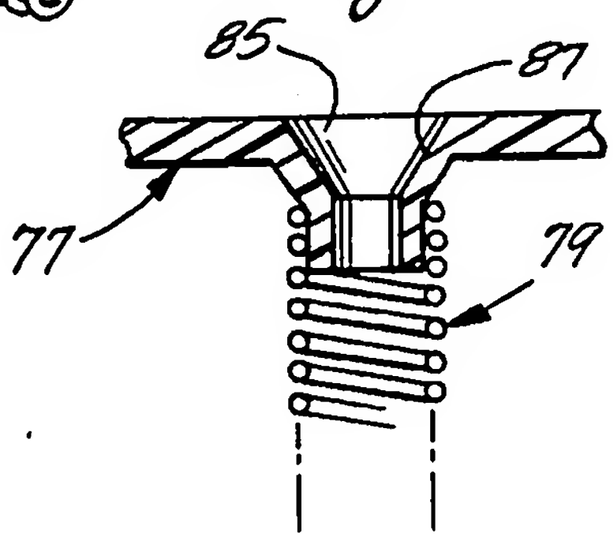


Fig 17

Fig 18



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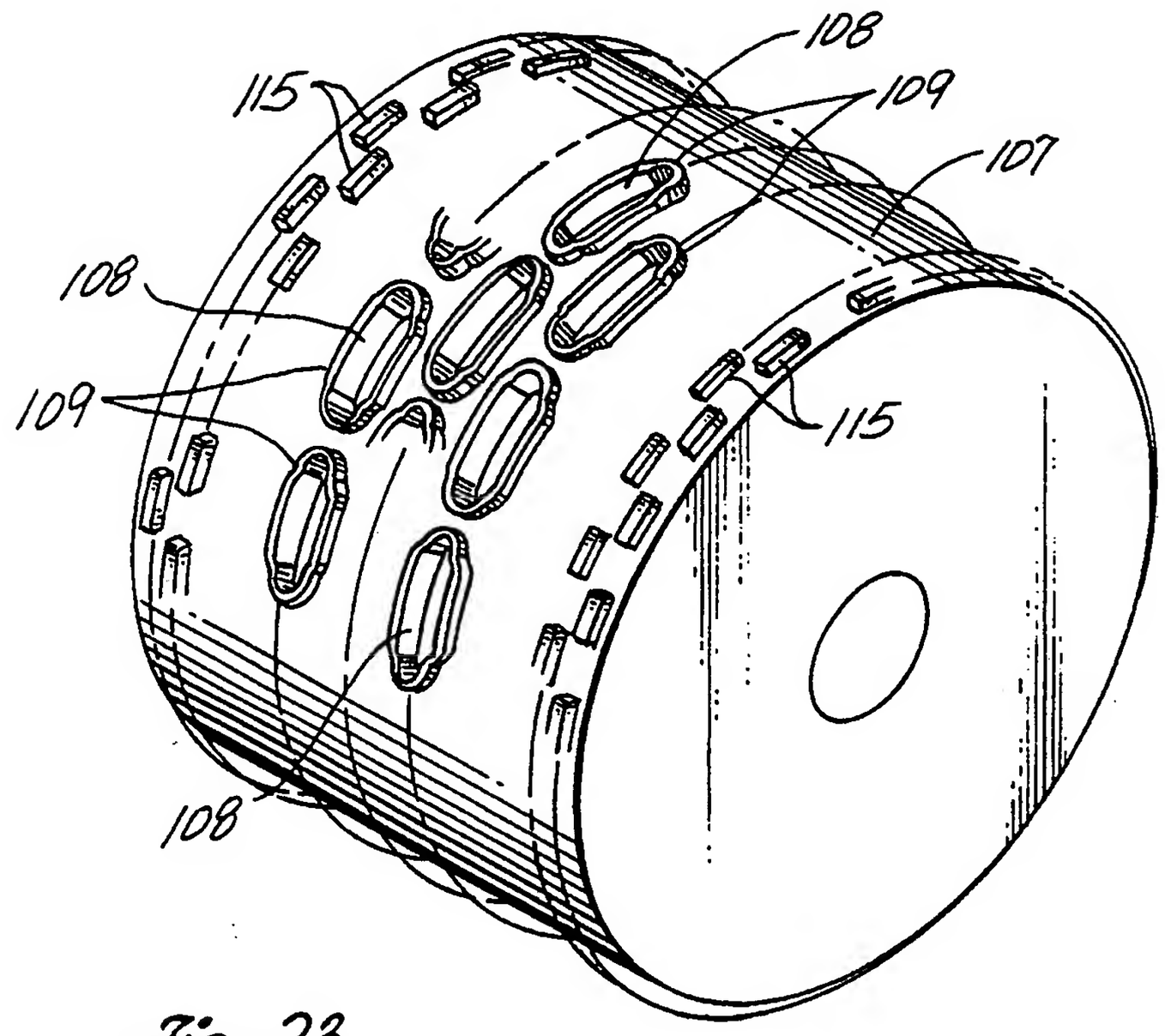

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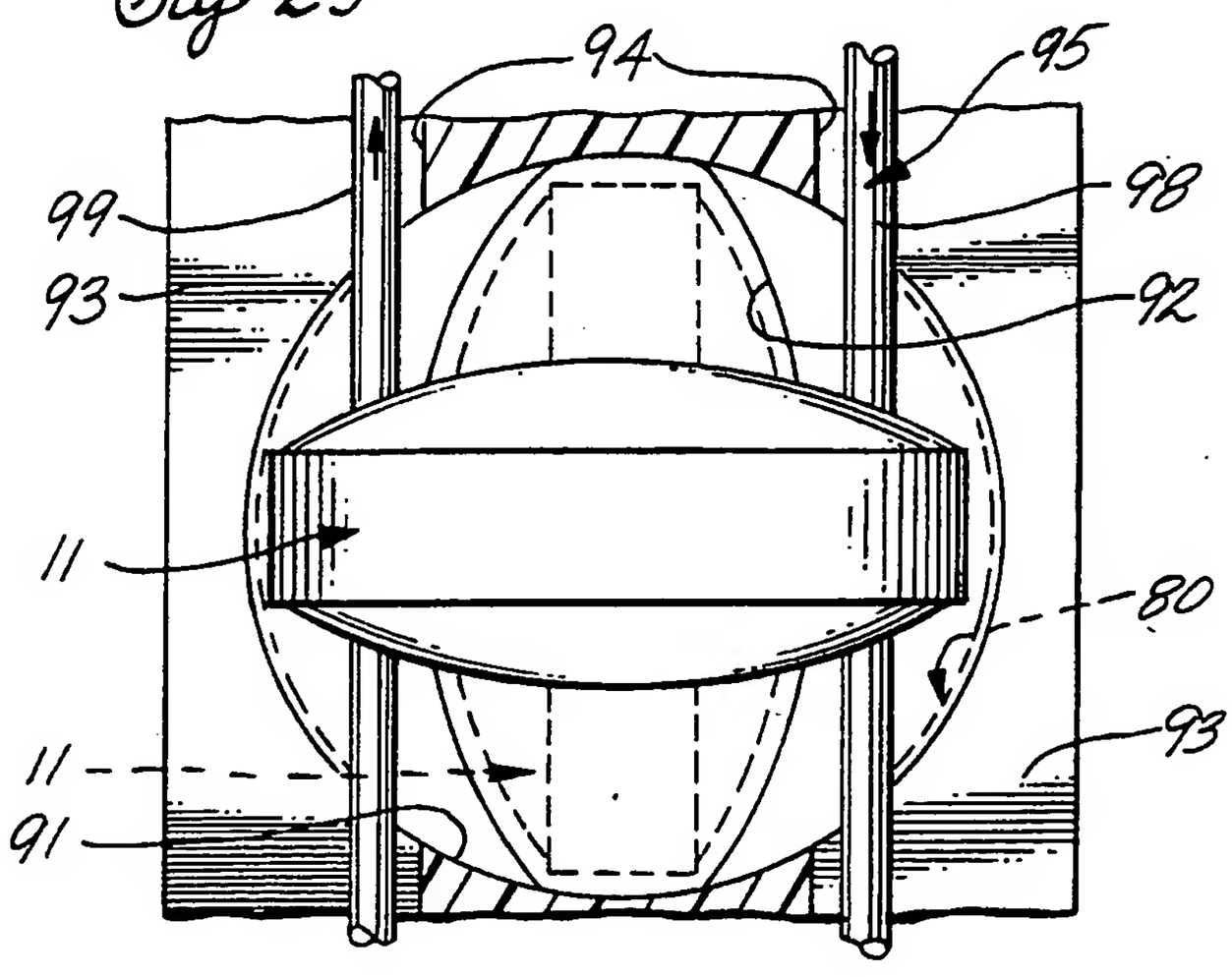
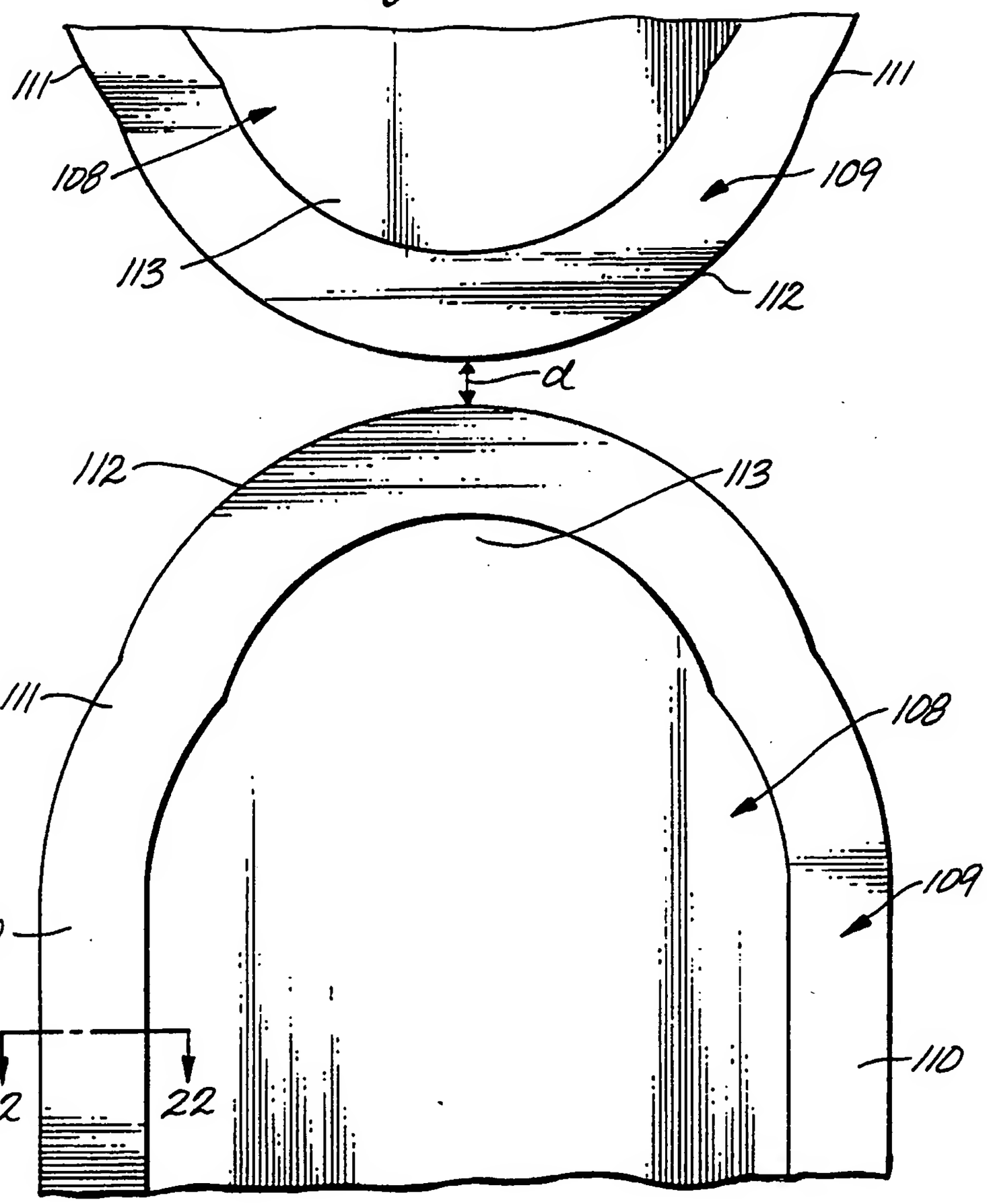


Fig 21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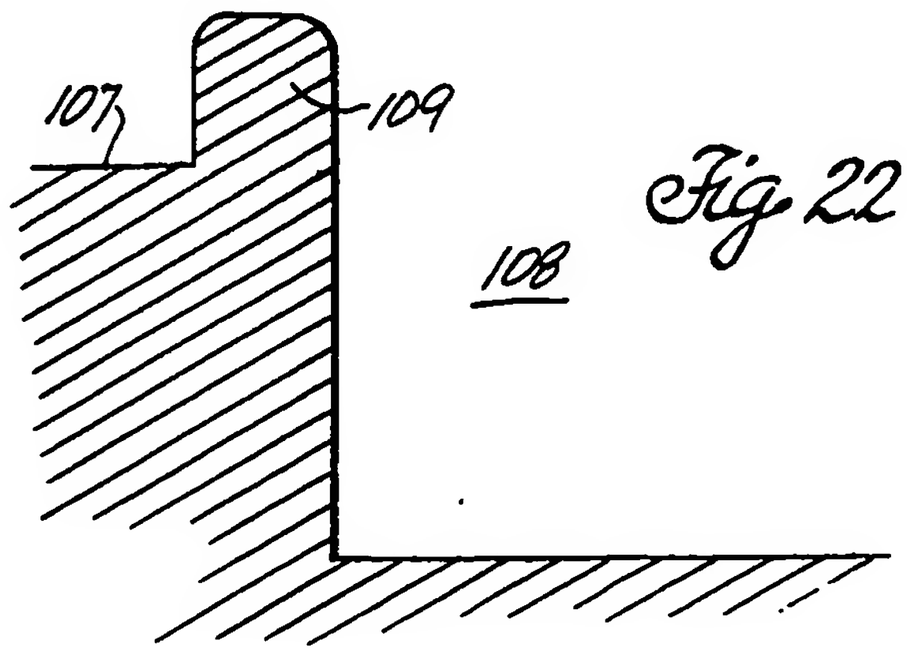
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Fig 22

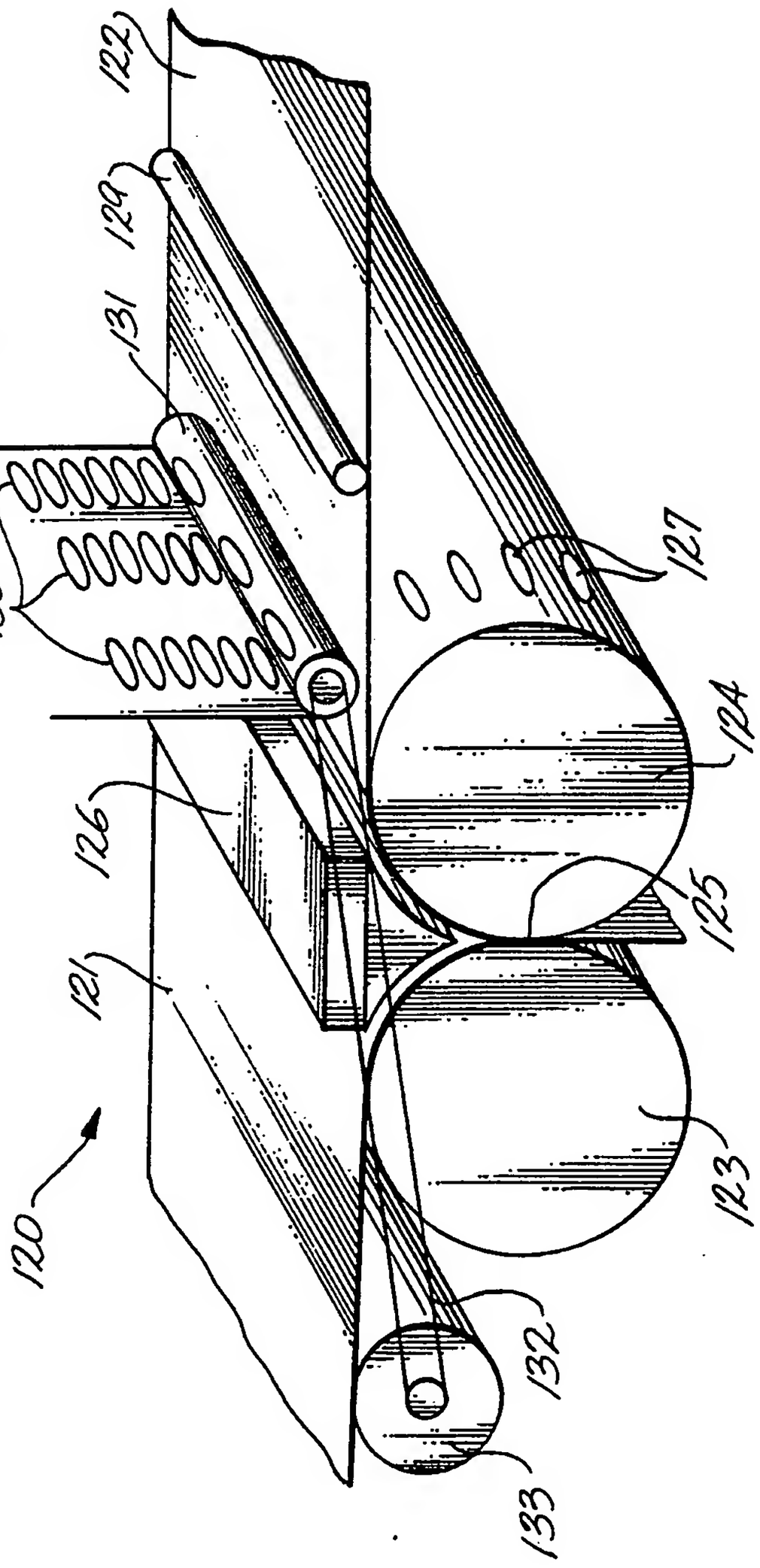


Fig 24

Fig. 25

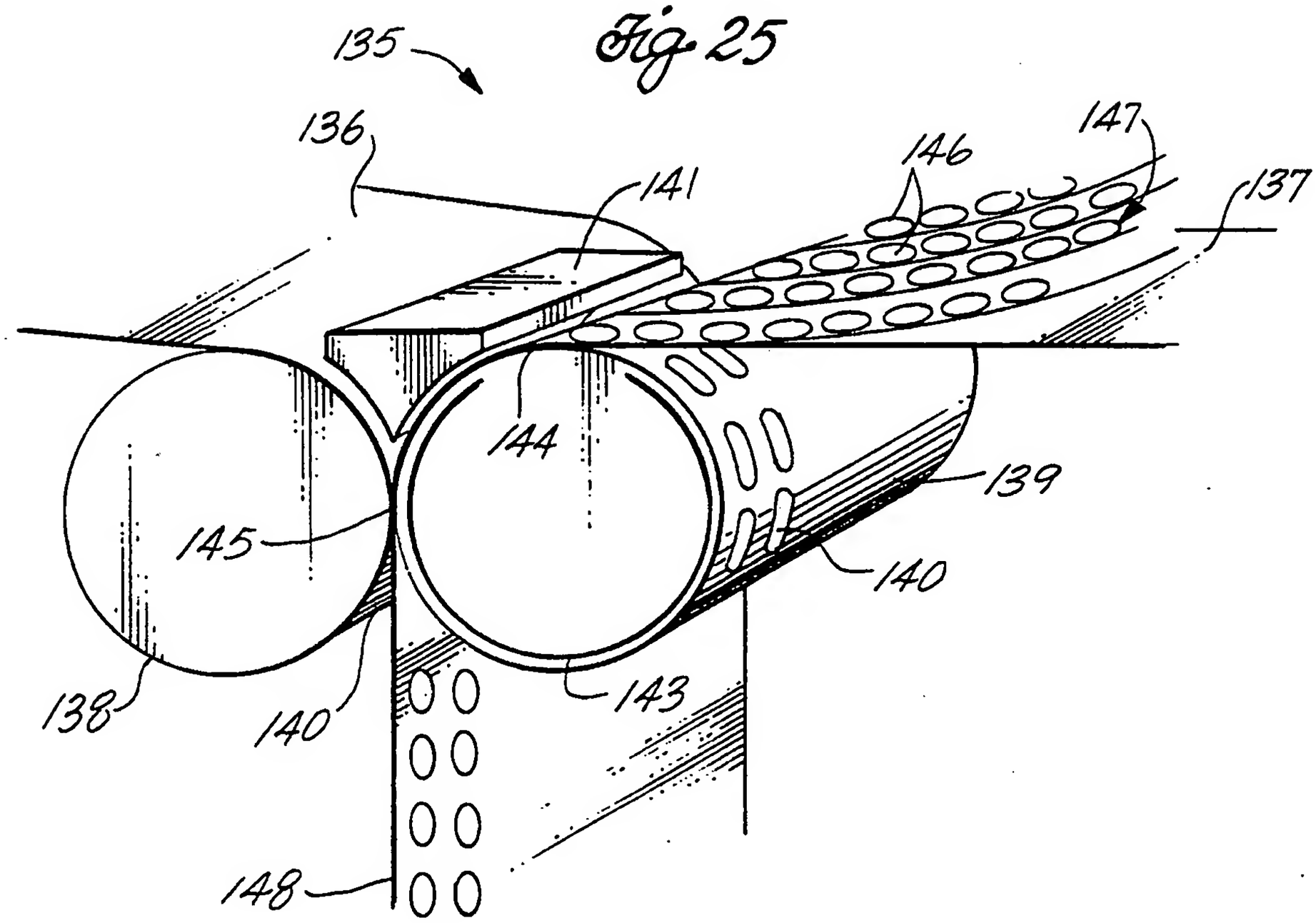
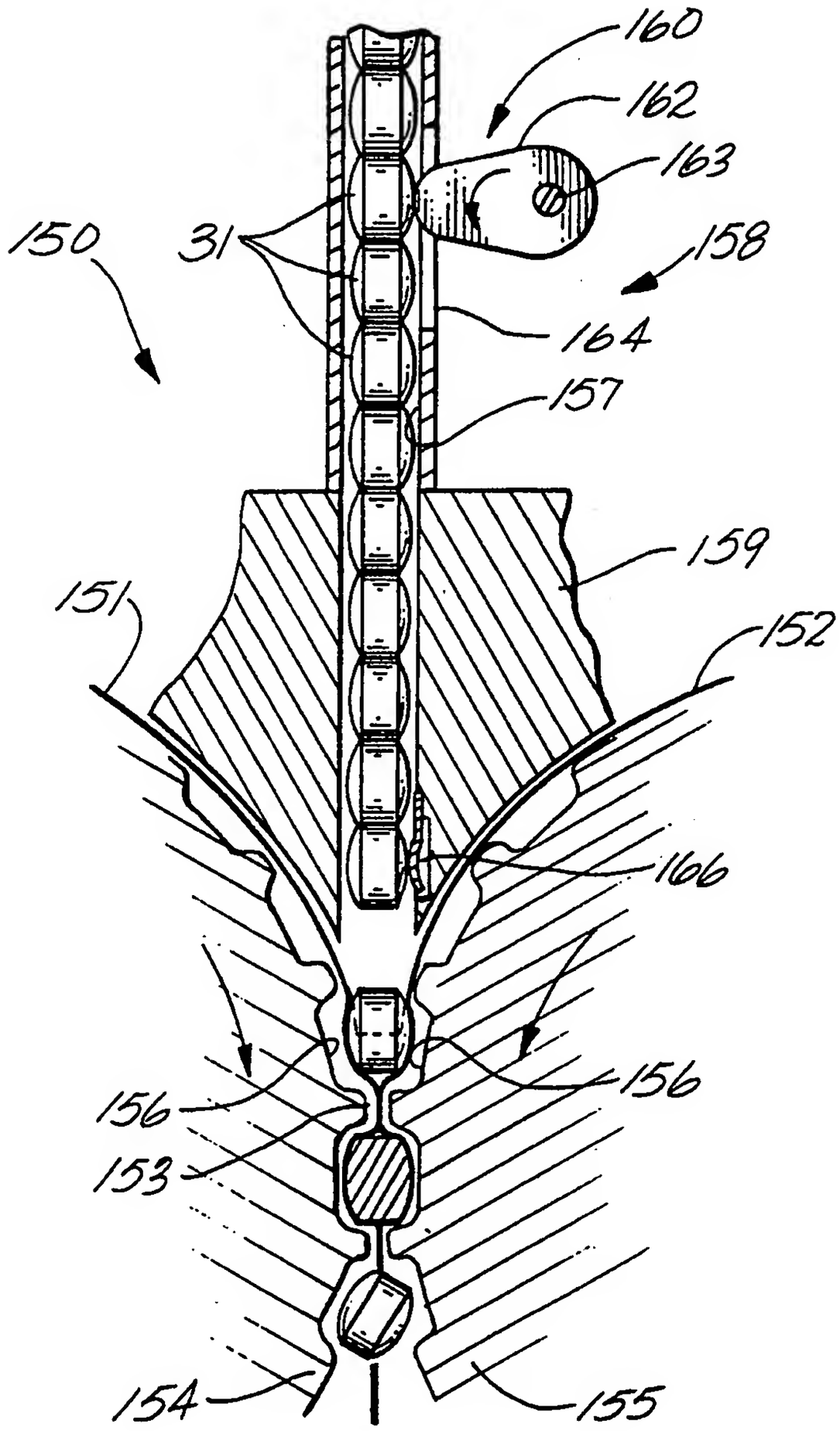


Fig. 26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INTERNATIONAL SEARCH REPORT

International Application No. PCT/US90/05373

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61K 9/24
U.S. CL. 424/464

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
U.S.	53/203; 106/125; 156/160, 190, 228, 229, 251, 302 156/552; 424/451, 456, 465; 428/403

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US, A, 2,608,405 (SALFISBERG) 26 AUGUST 1952 See entire document.	113-119
Y	US, A, 3,592,945 (ENGELKING) 13 JULY 1971 See entire document.	107-112
Y	US, A, 3,656,997 (CORDES) 18 APRIL 1972 See entire document.	71-80,83-94, 97-99, 102-106
Y	US, A, 3,692,562 (KAWATA) 19 SEPTEMBER 1972 See entire document.	1-52
Y	US, A, 4,670,287 (TSUJI) 02 JUNE 1987 See entire document.	71-80,83-94, 97-99, 102-112
Y	US, A, 4,782,647 (WILLIAMS) 08 NOVEMBER 1988 See entire document.	1-52
Y	US, A, 4,816,259 (MATTHEWS) 28 MARCH 1989 See entire document.	71-80,83-94, 97-99, 102-106
Y	GB, A, 0142638 (BEECHAM) 11 MARCH 1948 See entire document.	1, 71-80,83-94,97-99, 102-106

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search

29 DECEMBER 1990

Date of Mailing of this International Search Report

31 JAN 1991

International Searching Authority

ISA/US

Signature of Authorized Officer

Thurman K. Page

Form PCT/ISA/210 (second sheet) (Rev.11-87)